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14 **IN THE UNITED STATES DISTRICT COURT**  
15 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**  
16 **OAKLAND DIVISION**

17 STATE OF CALIFORNIA, *et al.*

18 Plaintiffs,

19 STATE OF OREGON

20 Plaintiff-Intervenor,

21 v.

22 ALEX M. AZAR, II, Secretary of Health  
and Human Services, *et al.*,

23 Defendants,

24 and

25 THE LITTLE SISTERS OF THE POOR,  
JEANNE JUGAN RESIDENCE, *et al.*

26 Defendant-Intervenors.

Case No. 4:17-cv-5783-HSG

**DEFENDANTS' MEMORANDUM IN  
SUPPORT OF MOTION TO DISMISS,  
OR IN THE ALTERNATIVE,  
MOTION FOR SUMMARY  
JUDGMENT, AND DEFENDANTS'  
OPPOSITION TO PLAINTIFFS'  
MOTION FOR SUMMARY  
JUDGMENT**

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Judge: Hon. Haywood S. Gilliam, Jr.

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## INTRODUCTION

As part of the Patient Protection and Affordable Care Act (ACA), Congress required employers to cover some recommended preventive services without cost sharing. That law does not mention contraceptive coverage. But the Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services (HHS), issued guidelines mandating coverage of all FDA-approved contraceptives. At the same time, the government recognized that some employers hold sincere religious objections to providing insurance coverage for some or all forms of contraception, but decided to exempt only a fraction of those employers—churches and their integrated auxiliaries—from the requirement. Other entities were not required to provide contraceptive coverage because they were grandfathered by the ACA. The Departments of HHS, Labor, and the Treasury (the Agencies) ultimately recognized that the contraceptive-coverage mandate imposed a substantial burden on the exercise of religion of certain entities, and attempted to alleviate that burden through an “accommodation.” But the accommodation still substantially burdened the religious exercise of some objecting entities, and years of litigation ensued.

To address these serious religious objections and to resolve the litigation, the Agencies promulgated final rules that expand the prior religious exemption and also provide for a moral exemption to the contraceptive-coverage mandate. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,536 (Nov. 15, 2018) (the Religious Exemption Rule); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the Moral Exemption Rule) (collectively, the Rules). The same provision of the ACA that authorized the Agencies to issue the prior exemption for churches and their integrated auxiliaries equally authorizes the expanded exemptions. Moreover, the Religious Freedom Restoration Act (RFRA) independently

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1 authorizes, and indeed requires, the religious exemption as a means of eliminating the substantial  
2 burden on religious exercise that *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), held  
3 was imposed by the contraceptive-coverage mandate.

4 Both RFRA and the ACA authorize the government to satisfy its obligations under RFRA  
5 by using the straightforward exemption provided by the Rules rather than attempting to rely only  
6 on the novel accommodation previously created by the government. That is especially true  
7 because the accommodation itself violates RFRA as to certain entities or is, at a minimum, subject  
8 to significant legal doubt: as the Agencies concluded and some courts have held, the  
9 accommodation imposes a substantial burden on some employers by using the plans they sponsor  
10 to provide contraceptive coverage that they object to on religious grounds, which some employers  
11 sincerely believe makes them complicit in the provision of such coverage.  
12

13 Furthermore, the Rules are not arbitrary and capricious under the Administrative Procedure  
14 Act (APA): The Rules are a reasonable response to years of litigation over the scope of the  
15 contraceptive-coverage mandate, well-founded in the evidence before the Agency, and responsive  
16 to the significant comments that were presented. The Rules also comply with the procedural  
17 requirements of the APA, as they were promulgated after notice and an opportunity for comment.  
18 Finally, the Rules comport with both the Establishment and Equal Protection Clauses, as they  
19 neither establish religion nor discriminate against women. The Court, therefore, should deny  
20 Plaintiffs' motion for summary judgment and grant Federal Defendants' motion to dismiss or, in  
21 the alternative, for summary judgment.  
22  
23

## 24 **BACKGROUND**

### 25 **I. The Affordable Care Act and the Contraceptive-Coverage Mandate.**

26 The ACA requires most group health plans and health-insurance issuers that offer group or  
27 individual health coverage to provide coverage for certain preventive services without "any cost

1 sharing requirements.” 42 U.S.C. § 300gg-13(a). The Act does not specify the types of women’s  
2 preventive care that must be covered. Instead, as relevant here, the Act requires coverage, “with  
3 respect to women,” of such “additional preventive care and screenings . . . as provided for in  
4 comprehensive guidelines supported by the Health Resources and Services Administration  
5 [“HRSA”].” *Id.* § 300gg-13(a)(4).

6 In August 2011, HRSA adopted the recommendation of the Institute of Medicine, a part of  
7 the National Academy of Sciences, to issue guidelines requiring coverage of, among other things,  
8 the full range of FDA-approved contraceptive methods, including oral contraceptives, diaphragms,  
9 injections and implants, emergency contraceptive drugs, and intrauterine devices. *See* 77 Fed.  
10 Reg. 8,725, 8,725 (Feb. 15, 2012). As a result, coverage for such contraceptive methods was  
11 required for plan years beginning on or after August 1, 2012. *See* 76 Fed. Reg. 46,621, 46,623  
12 (Aug. 3, 2011).

14 At the same time, the Agencies, invoking their statutory authority under 42 U.S.C. § 300gg-  
15 13(a)(4), promulgated interim final rules authorizing HRSA to exempt churches and their  
16 integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623; 77  
17 Fed. Reg. at 8,725. Various religious groups urged the Agencies to expand the exemption to all  
18 religious not-for-profit organizations and other organizations with religious or moral objections to  
19 providing contraceptive coverage. *See* 78 Fed. Reg. 8,456, 8,459 (Feb. 6, 2013). Instead, in a  
20 subsequent rulemaking, the Agencies offered only what they termed an “accommodation” for  
21 religious not-for-profit organizations with religious objections to providing contraceptive  
22 coverage. *See* 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a  
23 group health plan established or maintained by an eligible objecting employer to opt out of any  
24 requirement to directly “contract, arrange, pay, or refer for contraceptive coverage,” *id.* at 39,874,  
25  
26  
27

1 by providing notice of its objection. The regulations then generally required the employer's health  
2 insurer or third-party administrator to provide or arrange contraceptive coverage for plan  
3 participants. *See id.* at 39,875-80.

4 In the case of self-insured church plans, however, coverage by the plan's third-party  
5 administrator under the accommodation was voluntary.<sup>1</sup> Church plans are exempt from the  
6 Employee Retirement Income Security Act of 1974 (ERISA) under section 4(b)(2) of that Act, and  
7 the authority to enforce a third-party administrator's obligation to provide separate contraceptive  
8 coverage derives solely from ERISA. The Agencies thus could not require the third-party  
9 administrators of church plans—and, by extension, many nonprofit religious organizations  
10 participating in those plans—to provide or arrange for such coverage or impose fines or penalties  
11 for failing to provide such coverage. *See* 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

13 Even apart from the exemption for churches and their integrated auxiliaries, the  
14 contraceptive-coverage mandate did not apply to many employers. The ACA itself exempts from  
15 the preventive-services requirement, and therefore from any contraceptive-coverage mandate  
16 imposed as part of that requirement, “grandfathered” health plans (generally, those plans that have  
17 not made specified changes since the Act's enactment), *see* 42 U.S.C. § 18011, which cover tens  
18 of millions of people, *see* 83 Fed. Reg. 57,541 (Nov. 15, 2018) (estimating over 25 million  
19 individuals enrolled in such plans). And employers with fewer than fifty employees are not subject  
20 to the tax imposed on employers that fail to offer health coverage, *see* 26 U.S.C. § 4980H(c)(2),  
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25 <sup>1</sup> A church plan can include a plan maintained by a “principal purpose” organization regardless  
26 of who established it. *See Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1655-63  
(2017); *see also* 29 U.S.C. § 1002(33).



1 although such small employers that provide non-grandfathered coverage must comply with the  
2 preventive-services requirement.

## 3       **II.       Challenges to the Contraceptive-Coverage Mandate and Accommodation**

4       Many employers objected to the contraceptive-coverage mandate. In *Hobby Lobby*, the  
5 Supreme Court held that RFRA prohibited the government from applying the mandate to closely  
6 held for-profit companies with religious objections to providing contraceptive coverage. The  
7 Court held that the mandate “impose[d] a substantial burden on the exercise of religion” for  
8 employers with religious objections, 573 U.S. at 726, and that even assuming a compelling  
9 governmental interest, application of the mandate to such employers was not the least restrictive  
10 means of furthering that interest, *id.* at 728. The Court observed that, at a minimum, the less-  
11 restrictive accommodation made available to not-for-profit employers by the Agencies could be  
12 extended to closely held for-profit companies like Hobby Lobby with religious objections to the  
13 mandate but not the accommodation. *Id.* at 731-32. The Court did not decide, however, “whether  
14 an approach of this type complies with RFRA for purposes of all religious claims.” *Id.* at 731  
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17       In response to *Hobby Lobby*, the Agencies promulgated rules extending the  
18 accommodation to closely held for-profit entities with religious objections to providing  
19 contraceptive coverage. *See* 80 Fed. Reg. at 41,323-28 (July 14, 2015). But numerous entities  
20 continued to challenge the mandate and the accommodation. They argued that the accommodation  
21 burdened their exercise of religion because they sincerely believed that the required notice and the  
22 provision of contraceptive coverage in connection with their health plans made them complicit in  
23 providing such coverage, in contravention of their faith.  
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1 A circuit split developed,<sup>2</sup> and the Supreme Court granted certiorari in several of the cases.  
2 The Court vacated the judgments and remanded the cases to the respective courts of appeals. *See*  
3 *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam). The Court “d[id] not decide whether [the  
4 plaintiffs’] religious exercise ha[d] been substantially burdened, whether the Government ha[d] a  
5 compelling interest, or whether the current regulations [we]re the least restrictive means of serving  
6 that interest.” *Id.* at 1560. Instead, the Court held that, on remand, the Courts of Appeals should  
7 afford the parties an opportunity to resolve the dispute. In the meantime, the Court precluded the  
8 government from “impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice  
9 required under the accommodation].” *Id.* at 1561.

11 In response to the Supreme Court’s *Zubik* order, the Agencies requested public comment  
12 to determine whether further modifications to the accommodation could resolve the religious  
13 objections asserted by various organizations while providing a mechanism for coverage for their  
14 employees. *See* 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies received over 54,000  
15 comments, but they could not find a way to amend the accommodation to both account for  
16 employers’ religious objections and provide seamless coverage to their employees. *See* FAQs  
17 About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).<sup>3</sup> The pending litigation—  
18 more than three dozen cases brought by more than 100 separate plaintiffs—thus remained  
19 unresolved.  
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24 <sup>2</sup> Compare, e.g., *Priests for Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014) (accommodation does  
25 not substantially burden religious exercise), *vacated and remanded*, 136 S. Ct. 1557 (2016), with  
26 *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015) (accommodation violates RFRA),  
*vacated by HHS v. CNS Int’l Ministries*, 136 S. Ct. 2006 (2016).

27 <sup>3</sup> Available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.

1 In addition, some nonreligious organizations with moral objections to providing  
2 contraceptive coverage challenged the mandate. That litigation also led to conflicting decisions  
3 by the courts. *Compare Real Alternatives, Inc. v. Secretary, HHS*, 867 F.3d 338 (3d Cir. 2017)  
4 (rejecting challenge), with *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015) (issuing  
5 permanent injunction against the government).

### 6 **III. The Interim Final Rules**

7 In an effort “to resolve the pending litigation and prevent future litigation from similar  
8 plaintiffs,” the Agencies concluded that it was “appropriate to reexamine” the mandate’s  
9 exemption and accommodation. 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017). Following that  
10 reexamination, in October 2017, the Agencies issued two interim final rules, or IFRs, that  
11 requested public comments and that expanded the exemption while continuing to offer the existing  
12 accommodation as an optional alternative. The first rule expanded the religious exemption to all  
13 nongovernmental plan sponsors, as well as institutions of higher education in their arrangement of  
14 student health plans, to the extent that those entities have sincere religious objections to providing  
15 contraceptive coverage. *See id.* at 47,806. The Agencies relied in part on their consistent  
16 interpretation of the preventive-services provision to convey “broad discretion to decide the extent  
17 to which HRSA will provide for and support the coverage of additional women’s preventive care  
18 and screenings in the Guidelines.” *Id.* at 47,794.

21 The Agencies acknowledged that contraceptive coverage is “an important and highly  
22 sensitive issue, implicating many different views.” 82 Fed. Reg. at 47,799. But “[a]fter  
23 reconsidering the interests served by the [m]andate,” the “objections raised,” and “the applicable  
24 Federal law,” the Agencies “determined that an expanded exemption, rather than the existing  
25 accommodation, [wa]s the most appropriate administrative response to the religious objections  
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1 raised by certain entities and organizations.” *Id.* The Agencies also explained that the new  
 2 approach was necessary because “[d]espite multiple rounds of rulemaking,” and even more  
 3 litigation, they “ha[d] not assuaged the sincere religious objections to contraceptive coverage of  
 4 numerous organizations” or resolved the pending legal challenges that had divided the courts. *Id.*

5 The second rule created a similar exemption for entities with sincerely held moral  
 6 objections to providing contraceptive coverage; unlike the religious exemption, though, this rule  
 7 did not apply to publicly traded companies. *See* 82 Fed. Reg. 47,838 (Oct. 13, 2017). This rule  
 8 was issued “in part to bring the [m]andate into conformity with Congress’s long history of  
 9 providing or supporting conscience protections in the regulation of sensitive health-care issues,”  
 10 *id.* at 47,844, as well as similar efforts by states, including Plaintiffs, *id.* at 47,847. The IFR further  
 11 reflected the Agencies’ attempts to resolve legal challenges by moral objectors that had given rise  
 12 to conflicting court decisions. *Id.* at 47,843.

14 Invoking agency-specific statutory authority to issue interim final rules, 26 U.S.C. § 9833;  
 15 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92, the Agencies’ use of interim final rules on three prior  
 16 occasions with respect to the preventive service requirements, and the APA’s general “good cause”  
 17 exception, 5 U.S.C. § 553(b), the Agencies issued the IFRs without prior notice and comment.  
 18 The Agencies also solicited public comments for 60 days post-promulgation in anticipation of final  
 19 rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.

#### 21 **IV. Plaintiffs’ Challenge to the IFRs, the District Court’s Opinion, and the Ninth** 22 **Circuit’s Ruling**

23 California and four other states sued, challenging the IFRs. They claimed that the IFRs (1)  
 24 failed to comply with the APA’s notice-and-comment requirements; (2) were arbitrary and  
 25 capricious, an abuse of discretion, or otherwise contrary to law; (3) violated the Establishment  
 26

1 Clause; and (4) violated the Equal Protection Clause. Am. Compl., Nov. 1, 2017, ECF No. 24, ¶¶  
 2 116-137.

3 The Court granted Plaintiffs' motion for preliminary injunctive relief on the first claim,  
 4 issuing a "nationwide" preliminary injunction against the IFRs. Order Granting Pls.' Mot. for a  
 5 Prelim. Inj., Dec. 21, 2017, ECF No. 105, at 28-29. On December 13, 2018, the Ninth Circuit  
 6 affirmed the Court's decision in part and vacated it in part. *California v. Azar*, 911 F.3d 558 (9th  
 7 Cir. 2018). That court concluded that venue was proper in this district. *Id.* at 569. It also held  
 8 that Plaintiffs had standing to challenge the IFRs because the "states show[ed], with reasonable  
 9 probability, that the IFRs will first lead to women losing employer-sponsored contraceptive  
 10 coverage, which will then result in economic harm to the states." *Id.* at 571. Next, the Court of  
 11 Appeals decided that the Agencies "did not have statutory authority for bypassing notice and  
 12 comment" with respect to the IFRs, and that doing so was not harmless. *Id.* at 580-81. The Ninth  
 13 Circuit also held that the injunction "must be narrowed to redress only the injury shown as to the  
 14 plaintiff states." *Id.* at 584.

## 15 **V. The Final Rules**

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 17 After considering, for over 11 months, the more than 110,000 comments on the IFRs, on  
 18 November 15, 2018, the Agencies issued final versions of the Religious Exemption and the Moral  
 19 Exemption Rules. The final rules address the significant comments received by the Agencies.  
 20 Changes were made in response to questions and concerns raised in various comments, while the  
 21 fundamental substance of the exemptions was finalized as set forth in the IFRs.  
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 24 As was true of the IFR expanding the religious exemption, the final Religious Exemption  
 25 Rule is "necessary to expand the protections for the sincerely held religious objections of certain  
 26 entities." 83 Fed. Reg. at 57,537. It "minimize[s] the burdens imposed on their exercise of  
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1 religious beliefs, with regard to the discretionary requirement that health plans cover certain  
2 contraceptive services with no cost-sharing.” *Id.* The rule “do[es] not remove the contraceptive  
3 coverage requirement generally from HRSA’s Guidelines.” *Id.* What it does do is “finalize  
4 exemptions [for] the same types of organizations and individuals for which exemptions were  
5 provided in the Religious [IFR]: Non-governmental plan sponsors including a church, an  
6 integrated auxiliary of a church, a convention or association of churches, or a religious order; a  
7 nonprofit organization; for-profit entities; an institution of higher education in arranging student  
8 health insurance coverage; and, in certain circumstances, issuers and individuals.” *Id.* “In  
9 addition, the [religious exemption] maintain[s] a previously created accommodation process that  
10 permits entities with certain religious objections voluntarily to continue to object while the persons  
11 covered in their plans receive contraceptive coverage or payments arranged by their health  
12 insurance issuers or third party administrators.” *Id.*

14         In response to comments on the religious IFR, the Agencies made numerous clarifying or  
15 technical changes in the final Religious Exemption Rule. For example, the final rule clarified the  
16 prefatory language to the exemptions “to ensure exemptions apply to a group health plan  
17 established or maintained by an objecting organization, or health insurance coverage offered or  
18 arranged by an objecting organization, to the extent of the objections.” *Id.*; *see also id.* (listing  
19 modifications). The Agencies also “revise[d] the exemption applicable to health insurance issuers  
20 to make clear that the group health plan established or maintained by the plan sponsor with which  
21 the health insurance issuer contracts remains subject to any requirement to provide coverage for  
22 contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt  
23 from that requirement.” *Id.*

1 The final Moral Exemption Rule also continues to fulfill the purpose that it did in interim  
2 form: to “protect sincerely held moral objections of certain entities and individuals.” 83 Fed. Reg.  
3 at 57,592. The Agencies considered public comments asking for the moral exemption to be  
4 expanded to publicly traded or government entities, but declined to do so. *Id.* at 57,616-19.  
5 Importantly, like the Religious Exemption Rule, the Moral Exemption Rule “do[es] not remove  
6 the contraceptive coverage requirement generally from HRSA’s guidelines.” *Id.* at 57,593. But  
7 the Department made changes to the rule to “ensure clarity in implementation of the moral  
8 exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing  
9 this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise  
10 require contraceptive coverage.” *Id.*

## 12 **VI. Plaintiffs’ Second Amended Complaint and the Second Preliminary** 13 **Injunction**

14 Plaintiffs (joined by nine other states) filed a second amended complaint raising claims  
15 under the APA, the Establishment Clause, and the Equal Protection Clause. Second Am. Compl.,  
16 Dec. 18, 2018, ECF No. 170, ¶¶ 235-260. Plaintiffs also moved to preliminarily enjoin the Final  
17 Rules, but only with respect to their APA claims, not their constitutional claims.

18 The Court granted Plaintiffs’ motion for a preliminary injunction with respect to their APA  
19 claims. *California v. HHS*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019). As an initial matter, the Court  
20 rejected arguments that Plaintiffs had not demonstrated standing and that venue was not proper in  
21 the Northern District of California. *Id.* at 1280-84. The Court concluded that Plaintiffs were likely  
22 to succeed on their APA claims. *Id.* at 1284-97. However, the Court enjoined “the implementation  
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1 of the Final Rules in the Plaintiff States only.” *Id.* at 1301. Defendants have appealed that  
 2 decision;<sup>4</sup> the appeal is fully briefed, and the Ninth Circuit will hear argument on June 6, 2019.

### 3 LEGAL STANDARDS

4 A suit brought by a plaintiff without standing, as is the case here, should be dismissed for  
 5 lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1). *Cetacean Cmty. v. Bush*, 386  
 6 F.3d 1169, 1174 (9th Cir. 2004). If the Court determines that jurisdiction exists, then the Court  
 7 should dismiss Plaintiffs’ claims under the Women’s Health Amendment, the Constitution, and  
 8 the notice-and-comment requirement of the APA, for failure to state a claim upon which relief can  
 9 be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6). The Court should enter summary  
 10 judgment in favor of Defendants on the remainder of Plaintiffs’ claims under Federal Rule of Civil  
 11 Procedure 56.<sup>5</sup> “[D]istrict courts reviewing agency action under the . . . [APA] do not resolve  
 12 factual issues, but operate instead as appellate courts resolving legal questions.” *James Madison*  
 13 *Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). In other words, summary judgement  
 14 is an “appropriate mechanism” in an APA case for “determin[ing] whether or not as a matter of  
 15 law the evidence in the administrative record permitted the agency to make the decision it did.”  
 16 *Occidental Eng’g Co. v. I.N.S.*, 753 F.2d 766, 769 (9th Cir. 1985).  
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25 <sup>4</sup> An appeal of this second preliminary injunction has been docketed in the Ninth Circuit. See  
 26 *California v. Little Sisters of the Poor*, No. 19-15072, *California v. HHS*, No.19-15118, and  
 27 *California v. March for Life*, No. 1915150 (9th Cir. 2019).

<sup>5</sup> The Court could, of course, also enter summary judgment in favor of Federal Defendants on the  
 28 claims under the Women’s Health Amendment and the Constitution.



**ARGUMENT<sup>6</sup>**

**I. The Rules Are Consistent with the ACA<sup>7</sup>**

**A. The Rules Comport with the Women’s Health Amendment**

Plaintiffs’ argument that the Rules violate the Women’s Health Amendment, 42 U.S.C. § 300gg-13(a)(4), fails because the ACA grants HRSA, and in turn the Agencies, significant discretion to shape the content and scope of any preventive-services guidelines adopted pursuant to § 300gg-13(a)(4). Although this Court concluded that the Plaintiffs had shown a substantial likelihood of success on the merits with respect to this argument in resolving the Plaintiffs’ preliminary injunction motion, the Agencies respectfully urge this Court to consider this issue anew now that it is presented for decision on the merits at summary judgment. .

The ACA does not specify the types of preventive services that must be included in such guidelines. Instead, as relevant here, it provides only that, “with respect to women,” coverage

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<sup>6</sup> As a threshold matter, the Court should dismiss this case for lack of subject-matter jurisdiction. Defendants have previously explained that Plaintiffs lack standing to bring this suit. Defs.’ PI Opp., Nov. 29, 2017, ECF No. 51, at 8-12. The Court of Appeals concluded, at the preliminary injunction stage, that Plaintiffs had established standing. *California v. Azar*, 911 F.3d at 570-74. This case has now moved past the preliminary injunction stage, however, and the elements of standing must be “supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Yet Plaintiffs have provided no additional evidence to demonstrate standing, as they are required to do. As another court in this Circuit wrote: “While the Court previously concluded that both Plaintiffs . . . established standing at the preliminary injunction stage . . . their burden for doing so on summary judgment is more exacting and requires them to set forth ‘by affidavit or other evidence ‘specific facts’ such that a ‘fair-minded jury’ could find they have standing.” *Karnoski v. Trump*, No. C17-1297-MJP, 2018 WL 1784464, at \*7 (W.D. Wash. Apr. 13, 2018) (quoting *Lujan*, 504 U.S. at 561). Because Plaintiffs have not provided the evidence of standing needed to satisfy the “more exacting” standard applicable at summary judgment, they have not established standing to bring this suit.

<sup>7</sup> Plaintiffs’ motion for summary judgment also addresses the IFRs. But their challenges to the IFRs are moot. Regardless of the outcome of the litigation, the IFRs would not be enforced because they have been superseded by the Final Rules. *See Gulf of Me. Fishermen’s All. v. Daley*, 292 F.3d 84, 88 (1st Cir. 2002) (“[P]romulgation of new regulations and amendment of old regulations are among such intervening events as can moot a challenge to the regulation in its original form”).

1 must include “such additional preventive care and screenings . . . as provided for in  
2 comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a)(4). Several textual  
3 features of § 300gg-13(a) demonstrate that this provision grants HRSA broad discretionary  
4 authority, authority that the Agencies have recognized since HRSA first announced the  
5 contraceptive mandate and its accompanying church exemption.

6 First, unlike the other paragraphs of the statute, which require preventive-services  
7 coverage based on, *inter alia*, “current recommendations of the United States Preventive  
8 Services Task Force,” recommendations “in effect . . . from the Advisory Committee on  
9 Immunization Practices of the Centers for Disease Control and Prevention,” or “the  
10 comprehensive guidelines” that HRSA had already issued with respect to preventive care for  
11 children, the paragraph concerning preventive care for women refers to “comprehensive  
12 guidelines” that did not exist at the time of the ACA’s enactment. *Compare id.* § 300gg-  
13 13(a)(1), (2), (3), *with id.* § 300gg-13(a)(4). That paragraph thus necessarily delegated the  
14 content of the guidelines to HRSA.  
15

16 Second, nothing in the statute mandates that the guidelines include contraception at all,  
17 let alone include all types of contraception for all types of employers with covered plans. On the  
18 contrary, the statute provides only for coverage of preventive services “as provided for in  
19 comprehensive guidelines supported by [HRSA] for purposes of this paragraph.” *Id.* § 300gg-  
20 13(a)(4). The use of the phrase “for purposes of this paragraph” makes clear that HRSA should  
21 consider the particular context of the employer mandate in creating the guidelines, and the use of  
22 the phrase “as provided for” indicates that HRSA has discretion to define not only the services to  
23 be covered, but also the manner or reach of that coverage. *See also* 83 Fed. Reg. at 57,540 n.10;  
24 57,541 (discussing the Agencies’ interpretation of the word “as” to confer discretion on the  
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1 Agencies). The broad discretion granted to HRSA is further reinforced by the absence of the  
2 words “evidence-based” or “evidence-informed” in this subsection, as compared with § 300gg-  
3 13(a)(1), (3), which confirms that Congress authorized HRSA to consider factors beyond the  
4 scientific evidence in deciding whether to support a coverage mandate for particular preventive  
5 services.

6 Accordingly, § 300gg-13(a)(4) must be understood as a positive grant of authority for  
7 HRSA to develop the women’s preventive-services guidelines and for the Agencies, as the  
8 administering Agencies of the applicable statutes, to shape that development.<sup>8</sup> *See* 26 U.S.C.  
9 § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. That is especially true for HHS, as HRSA is  
10 a component of HHS that HHS created and that is subject to the HHS Secretary’s general  
11 supervision. *See* HRSA; Statement of Organization, Functions, and Delegations of Authority, 47  
12 Fed. Reg. 38,409 (Aug. 31, 1982). The text of § 300gg-13(a)(4) thus authorized HRSA to adopt  
13 guidelines for coverage that include an exemption for certain employers, and nothing in the ACA  
14 prevents HHS from supervising HRSA in the development of those guidelines. Indeed, since  
15 their first rulemaking on this subject in 2011, the Agencies have consistently interpreted the  
16 broad delegation to HRSA in § 300gg-13(a)(4) to include the authority to reconcile the ACA’s  
17 preventive-services requirement with sincerely held views of conscience on the sensitive subject  
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23 <sup>8</sup> Contrary to Plaintiffs’ argument, Plaintiffs’ Memorandum in Support of Motion for Summary  
24 Judgment (SJ Mem.), ECF No. 311, at 9, it is § 300gg-13(a) that authorizes the exemption for  
25 churches and their integrated auxiliaries, not the Internal Revenue Code. Indeed, the relevant  
26 Internal Revenue Code provisions, 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i) & (iii), are wholly  
27 unrelated to the provision of contraceptive coverage. Although the Agencies borrowed the  
28 definition of a “religious employer” from § 6033 when exercising their authority under 42 U.S.C.  
§ 300gg-13(a) to provide the exemption for churches and their integrated auxiliaries, nothing in §  
6033 serves as an independent source of authority for the government to create exemptions.

1 of contraceptive coverage by exempting churches and their integrated auxiliaries from the  
2 contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623.

3 In light of this statutory and regulatory backdrop, the Agencies' exercise of authority to  
4 expand the exemption is, at the very least, a reasonable construction of the statute entitled to  
5 deference. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43  
6 (1984). Under Step Two of the Chevron doctrine, a court must defer to an agency's reasonable  
7 interpretation of an ambiguous statute. *Id.* at 843 (" . . . if the statute is silent or ambiguous with  
8 respect to the specific issue, the question for the court is whether the agency's answer is based on  
9 a permissible construction of the statute"). An agency is entitled to Chevron deference not only  
10 with regard to interpretations of substantive law, but also with regard to the scope of that  
11 agency's jurisdiction. *City of Arlington v. FCC*, 569 U.S. 290 (2013). Hence, if this Court  
12 concludes that the statute is ambiguous as to whether it provides the Agencies with discretion to  
13 create or modify contraceptive coverage exemptions, the Agencies' construction must prevail  
14 because it is a reasonable one.  
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16  
17 Plaintiffs' arguments to the contrary are unavailing. Plaintiffs argue that Congress's  
18 exemption of certain employers with grandfathered plans, and its rejection of a conscience  
19 amendment, mean that the statute should be read to preclude the creation of religious or moral  
20 exemptions. With respect to grandfathered plans, they are significant but not for the reasons  
21 Plaintiffs assert. The grandfathering exemption demonstrates that Congress did not intend fully  
22 uniform coverage of preventive services across all employers, which is consistent with the  
23 Agencies' interpretation of the statute: although grandfathered plans are required to comply with  
24 numerous provisions of the ACA, they are exempted from the law's requirement to provide  
25 coverage for preventive services. *See* 83 Fed. Reg. 57,541. And no federal law requires phasing  
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1 out of the exemption for grandfathered plans. *See Hobby Lobby*, 572 U.S. at 700 n.10. In light  
2 of Congress’ decision to provide exemptions from all preventive services coverage for  
3 grandfathered plans, it is not unreasonable to interpret the statute to also provide the Agencies  
4 with discretion to create exemptions for certain preventive services for religious and moral  
5 objectors.

6 Nor should the rejection of a conscience amendment bear on this Court’s assessment of  
7 the meaning of § 300gg-13(a)(4). “Failed legislative proposals are a particularly dangerous  
8 ground on which to rest an interpretation of a prior statute.” *Cent. Bank of Denver, N.A. v. First*  
9 *Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (citation omitted). Congress may  
10 decline to adopt a proposal for any number of reasons, including “that the existing legislation  
11 already incorporated the offered change.” *Id.* *See also* 158 Cong. Rec. S485 (Feb. 9, 2012)  
12 (statement of Sen. Reid) (“They are talking about first amendment rights, the Constitution. I  
13 appreciate that. But that is so senseless. This debate that is going on dealing with this issue,  
14 dealing with contraception, is a rule that has not been made final yet. There is no final rule.  
15 Let’s wait until there is at least a rule we can talk about.”).

16 Plaintiffs further argue, without explanation, that the statute should be read to preclude  
17 the moral and religious exemptions because the ACA elsewhere prohibits “unreasonable  
18 barriers” to medical care and requires “timely access” to medical care. *See* SJ Mem. at 18 (citing  
19 42 U.S.C. § 18114(1), (2)). But, as described *infra*, (Argument § 1.B), those provisions have not  
20 been violated. The Rules merely narrow the scope of employers subject to the contraceptive-  
21 coverage mandate rather than impose any affirmative barriers on access to contraception. *Cf.*  
22 *Harris v. McRae*, 448 U.S. 297, 316 (1980) (“[A]lthough government may not place obstacles in  
23 the path of a woman’s exercise of her freedom of choice, it need not remove those not of its own  
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1 creation[, such as indigency].”). In addition, Plaintiffs do not even argue that the purported  
2 barrier is unreasonable, nor that the Rules impede the timeliness of care—a difficult showing  
3 given the numerous other programs providing contraception, *see* 82 Fed. Reg. at 47,803, and the  
4 continued availability of the accommodation. Finally, the fact that the Women’s Health  
5 Amendment was added to the ACA after § 18114 demonstrates that § 18114 should not be  
6 understood to provide an alternative mandate for preventive or contraceptive coverage. Compare  
7 155 Cong. Rec. S11607, S11646 (daily ed. Nov. 19, 2009) (including the non-discrimination  
8 provision at § 1557 and the barriers provision at § 1554) with 155 Cong. Rec. S12265, S12277  
9 (daily ed. Dec. 3, 2009) (adding the Women’s Health Amendment).

11 Nor have the Agencies ignored the preventive service provision’s purpose. *See* SJ Mem.  
12 at 18. Plaintiffs take one broad statutory purpose—to increase access to preventive care—then  
13 focus myopically on one preventive service included in HRSA’s guidance and elevate it above  
14 all others. “But no legislation pursues its purposes at all costs. Deciding what competing values  
15 will or will not be sacrificed to the achievement of a particular objective is the very essence of  
16 legislative choice . . . .” *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987).

18 Notwithstanding Plaintiffs’ claim to the contrary, the Agencies did, in fact, consider the interests  
19 advanced by the Women’s Health Amendment in deciding to issue the Rules. Indeed, HRSA  
20 kept the mandate in place for nearly all applicable entities, and HRSA included no exemptions  
21 for the other types of preventive services (included in its guidelines) to which conscience  
22 exemptions have not been asserted. The Agencies simply did not construe the Women’s Health  
23 Amendment to require them to pursue marginal advances to the interests served by that provision  
24 at the expense of all other interests. *See, e.g.*, 83 Fed. Reg. 57,556 (“[W]e conclude that the best  
25 way to balance the various policy interests at stake . . . is to provide the expanded exemptions set  
26

1 forth herein . . .”). Plaintiffs’ argument ignores that Congress has long recognized the need for  
 2 protecting objections of conscience in the area of health care, and also ignores the purposes of  
 3 RFRA in the Agency’s interpretation of the statute. *See infra*, Part II. As demonstrated in the  
 4 Rules themselves, Congress has protected conscientious objections over many decades, including  
 5 those based on religious beliefs, in the context of health care and coverage, even as it has sought  
 6 to promote and expand access to health services. *See* 83 Fed. Reg. at 57,538-39 n.1 (listing  
 7 conscience protections in federal health care laws). The decision to issue the Final Rules does  
 8 not contravene the purpose of § 300gg-13(a)(4).  
 9

10 Finally, Plaintiffs argue that the Final Rules are contrary to separation of powers  
 11 principles, because Plaintiffs contend that the Agency’s position would allow HRSA to exempt  
 12 “any and all” employers from coverage. *See* SJ Mem. at 20. But the Court need not decide what  
 13 the outer bounds of HRSA’s discretion are, as its actions here lie well within its authority under  
 14 the statute. And in any event, the ACA does not require HRSA to include contraceptives in the  
 15 Guidelines, so there is, by extension, no general prohibition on HRSA exercising its lesser  
 16 authority to include contraceptives in the Guidelines in a more limited fashion. The APA’s  
 17 arbitrary and capricious standard requires only that HRSA act rationally – as it has here, for all of  
 18 the reasons explained in the Final Rules. Ultimately, Plaintiffs’ argument regarding separation  
 19 of powers is based on the contention that the Agencies have misread an unambiguous statute, *see*  
 20 SJ Mem at 20, but as discussed above, the Agencies’ reading of the statute is correct, or at the  
 21 very least, a reasonable interpretation of statutory ambiguity.  
 22  
 23

#### 24 **B. The Rules Otherwise Comply with the ACA**

25 The Rules do not violate the ACA’s nondiscrimination requirement, 42 U.S.C. § 18116, or  
 26 its prohibition on unreasonable barriers to healthcare, § 18114. *See* SJ Mem. at 35-37. With  
 27 respect to section 18116, as explained below, the Rules do not discriminate on the basis of sex,  
 28 FEDERAL DEFS.’ MEM. IN SUPPORT OF MOT. TO DISMISS, MOT. FOR SUMM. J., AND OPP. TO  
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1 facially or otherwise. *See infra* Argument § 5 (“The Rules are Consistent with the Equal Protection  
 2 Clause”). With respect to section 18114, the Rules do not “(1) create[] any unreasonable barriers  
 3 to the ability of individuals to obtain appropriate medical care; [or] (2) impede[] timely access to  
 4 health care services.” 42 U.S.C. § 18114(1), (2).

5 As an initial matter, the sub-sections of section 18114 are quite open-ended. Nothing in  
 6 section 18114 specifies, for example, what constitutes an “unreasonable barrier[],” “appropriate  
 7 medical care[],” or “timely access.” As far as Defendants are aware, this provision was not the  
 8 subject of any meaningful legislative history before the ACA’s enactment, and Plaintiffs provide  
 9 none. Under these circumstances, section 18114 claims are not reviewable under the APA at all.  
 10 *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (APA bars judicial  
 11 review of agency decision where, among other circumstances, “statutes are drawn in such broad  
 12 terms that in a given case there is no law to apply” (citation omitted)).

13  
 14 In any event, the Rules do not implicate section 18114 because “the decision not to impose  
 15 a governmental mandate is not the ‘creation’ of a barrier.” 83 Fed. Reg. at 57,552. . The Rules  
 16 do not prevent women from obtaining medical care, including contraceptive care. They merely  
 17 provide that certain employers need not furnish cost-free *coverage* for such services to their  
 18 employees when doing so violates the employers’ religious or moral convictions. *Cf. Harris v.*  
 19 *McRae*, 448 U.S. at 316 (“[A]lthough government may not place obstacles in the path of a  
 20 woman’s exercise of her freedom of choice, it need not remove those not of its own creation[, such  
 21 as indigency].”).<sup>9</sup>  
 22  
 23  
 24  
 25

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26  
 27 <sup>9</sup> Free or low-cost contraceptives can be obtained by some women through other means, such as  
 Medicaid or the use of clinics that receive Title X funds.



Furthermore, under Plaintiffs' interpretation, section 18114 would mandate the provision of all "appropriate medical care," rendering the ACA's extensive discussion of Essential Health Benefits surplusage. *See generally* 42 U.S.C. §§ 18021, 18022. Even within the ACA, HHS routinely issues regulations placing criteria and limits on what must be covered in ACA programs. Under Plaintiffs' standardless interpretation of section 18114, it is far from clear that the government could ever impose any limits on the extent to which certain services must be covered or how a court could possibly evaluate such challenges.

**C. The Moral Exemption Rule is Not Contrary to Law, and is Grounded in the Agencies' Discretion under the § 300gg-13(a)(4)**

Plaintiffs argue that the Agencies "do not point to a specific congressional enactment authorizing [them] to promulgate the Moral Exemption Rule." SJ Mem. at 35. Not so. The Agencies have clearly invoked the discretion provide by § 300gg-13(a)(4) to promulgate the Moral Exemption Rule. *See e.g.*, 83 Fed. Reg. at 57,598; *see also supra* Part A. Plaintiffs also argue that the Agencies improperly highlighted the existence of a euthanasia provision elsewhere in the ACA to support the Moral Exemption Rule. *See* SJ Mem. at 35. But this provision simply illustrates that Congress did, in fact, contemplate the existence of exemptions based on moral convictions in the health care context, and supports the Agencies' conclusion that "providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress's intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts." *See* 83 Fed. Reg. 57,601.

**II. RFRA Authorizes (and Indeed Compels) the Religious Exemption Rule**

RFRA independently authorizes the religious exemption. RFRA prohibits the government

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1 from “substantially burden[ing] a person’s exercise of religion” unless the application of the  
 2 burden to that person is “the least restrictive means” of furthering a “compelling governmental  
 3 interest.” 42 U.S.C. § 2000bb-1(b). RFRA thus requires the government to eliminate any  
 4 substantial burden imposed by the contraceptive-coverage mandate, including the substantial  
 5 burden recognized by the Supreme Court in *Hobby Lobby*. The expanded religious exemption is  
 6 a permissible—and in the case of some objecting employers, required—means of doing so.

7  
 8 RFRA authorizes agencies to proactively create exemptions to avoid substantially  
 9 burdening religious exercise, just as the Agencies here did with the original exemption and  
 10 accommodation, which are not challenged by Plaintiffs. The Agencies were not required to  
 11 repeatedly amend the accommodation in response to litigation in an attempt to find the singular  
 12 accommodation that would be *least* protective of objectors’ religious exercise while still prevailing  
 13 in a RFRA lawsuit brought by objectors (even assuming such an accommodation could be found).  
 14 Put another way, RFRA authorizes the Agencies to provide an exemption to eliminate the  
 15 substantial burden imposed by the mandate rather than continue the protracted litigation that has  
 16 thus far been the hallmark of the contraceptive-coverage mandate.

#### 18 **A. Religious Objectors are Substantially Burdened in the Absence of the** 19 **Religious Exemption Rule**

20 The Religious Exemption Rule is necessary to alleviate the substantial burden that some  
 21 employers would otherwise face under the accommodation. These employers have “a sincere  
 22 religious belief that their participation in the accommodation process makes them morally and  
 23 spiritually complicit” in providing contraceptive coverage, because their “self-certification”  
 24 triggers “the provision of objectionable coverage through their group health plans.” *See Sharpe*  
 25 *Holdings, Inc. v. HHS*, 801 F.3d 927, 942 (8th Cir. 2015), *vacated and remanded sub nom. HHS*  
 26 *v. CNS Int’l Ministries*, 136 S. Ct. 2006 (2016) (mem.); *see also* 82 Fed. Reg. at 47,798, 47,800.

1 In light of that sincere religious belief, forcing objecting employers to violate that belief by using  
2 the accommodation or incur substantial financial penalties constitutes a substantial burden under  
3 *Hobby Lobby*. *Sharpe*, 801 F.3d at 939-43; *Priests for Life v. HHS*, 808 F.3d 1, 16-21 (D.C. Cir.  
4 2015) (Kavanaugh, J., dissenting from denial of rehearing en banc). Faced with this substantial  
5 burden, the Agencies previously determined that they could not find a way to amend the  
6 accommodation to both satisfy objecting organizations and provide seamless coverage to their  
7 employees. See FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).<sup>10</sup>  
8 And on further examination the Agencies determined that “that the application of the Mandate to  
9 certain objecting employers was [not] necessary to serve a compelling governmental interest.” 83  
10 Fed. Reg. 57,546. In such circumstances, RFRA requires the burden to be lifted.

12 Plaintiffs’ argument that the accommodation does not substantially burden religious  
13 practice, SJ Mem. at 22-26, 29, invites precisely what RFRA does not allow and what the Supreme  
14 Court has prohibited: “it is not for [a court] to say that [an objector’s] religious beliefs are  
15 mistaken.” *Hobby Lobby*, 573 U.S. at 725. As this Court acknowledged, “[u]nder RFRA, a  
16 substantial burden is imposed only when individuals are forced to choose between following the  
17 tenets of their religion and receiving a governmental benefit . . . or coerced to act contrary to their  
18 religious beliefs by the threat of civil or criminal sanctions . . . .” Order Granting Pls.’ Mot. PI,  
19 ECF No. 234, at 25 (quoting *Navajo Nation v. United States Forest Serv.*, 535 F.3d 1058, 1070  
20 (9th Cir. 2008) (internal quotation marks omitted)). Here, entities with sincere religious objections  
21 to the accommodation face just such coercion when they are forced to choose between using that  
22 accommodation or facing severe financial penalties for failing to provide contraceptive coverage.  
23  
24  
25

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26 <sup>10</sup> Available at [https://www.dol.gov/sites/default/files/ebsa/aboutebsa/](https://www.dol.gov/sites/default/files/ebsa/aboutebsa/our-activities/resource-center/faqs/aca-part-36.pdf)  
27 [our-activities/resource-center/faqs/aca-part-36.pdf](https://www.dol.gov/sites/default/files/ebsa/aboutebsa/our-activities/resource-center/faqs/aca-part-36.pdf)

Employers with religious objections to the accommodation sincerely believe that the “accommodation process itself triggers the provision of objectionable coverage . . . making them complicit in conduct that violates their religious beliefs.” *Sharpe Holdings*, 801 F.3d at 939. And *Hobby Lobby* establishes that a court’s “narrow function in this context is to determine whether the line drawn [by a religious objector] reflects an honest conviction,” as opposed to “in effect tell[ing] the plaintiffs that their beliefs are flawed.” 573 U.S. at 724, 725 (cleaned up).<sup>11</sup>

Plaintiffs also incorrectly assert that the Agencies ignored the requirement that a burden be substantial under RFRA. SJ Mem. at 22-23. Not so. As *Hobby Lobby* illustrates, where a court has held that the plaintiff has identified a sincerely held religious belief that a law requires it to violate, the court then determines whether the claimed burden is substantial—an independent inquiry that turns on the severity of the pressure the government’s action imposes on the objector’s religious exercise. *See* 573 U.S. at 719-20; *see also Sharpe*, 801 F.3d at 938. Here, the analysis is straightforward because the substantial burden resulting from the accommodation is the significant financial penalty imposed for failure to comply with the mandate or accommodation. That is the same penalty the plaintiffs faced in *Hobby Lobby*, where the Court had “little trouble” concluding that the mandate imposed a substantial burden. 573 U.S. 719; *see also Priests for Life*, 808 F.3d at 16 (Kavanaugh, J., dissenting from denial of rehearing en banc).

Plaintiffs argue that a parade of horrors would result if the Court—as it must—gave credence to the objecting entities’ view that their religious beliefs are violated. SJ Mem. at 24.

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<sup>11</sup> Plaintiffs assert that the Court in *Hobby Lobby* suggested that the accommodation did not impose a substantial burden on religious exercise. SJ Mem. at 26. But *Hobby Lobby* noted only that the accommodation satisfied the religious objections of the plaintiffs in that case, *see* 134 S. Ct. at 2782, not that the accommodation would satisfy the religious objections of other employers. Indeed, the Court made clear that it did not “decide today whether an approach of this type [i.e., the accommodation] complies with RFRA for purposes of all religious claims.” *Id.*

Yet Plaintiffs' concerns are illogical. For example, the States raise the hypothetical of "a religious conscientious objector to the military draft" objecting to "notifying the government of his religious opposition," SJ Mem. at 24, but that hypothetical is doubly inapposite: the military's drafting of a replacement would not violate the objector's religious exercise, because it would neither depend on the form of the objector's notification nor involve the objector's own contracts, and the government's need to conscript citizens to fight a war, unlike its purported need to conscript employers to subsidize their employees' contraception, would undoubtedly serve a compelling governmental interest, *see, e.g., Eternal Word Television Network, Inc. v. Secretary of HHS*, 818 F.3d 1122, 1188 n.32 (11th Cir. 2016) (Tjoflat, J., dissenting) (rejecting the draft hypothetical), *vacated*, No. 14-12696, 2016 WL 11503064 (11th Cir. May 31, 2016).

**B. There Is No Compelling Government Interest in Forcing Employers With Religious Objections to Provide Contraceptive Coverage**

Contrary to Plaintiffs' position, SJ Mem. 26-29, the Agencies reasonably concluded that there is no compelling interest that justifies the imposition of this substantial burden on the exercise of religion. The existence of a compelling interest is measured not by the governmental interests served by the mandate in general, but only the governmental interests served by applying the mandate to the small percentage of employers with sincere religious objections to it. *Hobby Lobby*, 573 U.S. at 725-26. In the Rules, the Agencies provided multiple reasons for their conclusion that application of the mandate to objecting entities neither serves a compelling governmental interest nor is narrowly tailored to any such interest:

1. Congress did not mandate coverage of contraceptives. 83 Fed. Reg. at 57,546-47.
2. Many other health plans are not required to provide contraceptive coverage apart from the Rule, including grandfathered plans, exempt churches and their integrated auxiliaries, and self-insured church plans that availed themselves of the accommodation. *Id.* at 57,547; *cf.*

1 *Advocate Health Care Network*, 137 S. Ct. at 1658-59.

2 3. In the Agencies' expert view, the administrative record does not contain adequate  
3 evidence to meet the high standard of demonstrating a compelling interest, 83 Fed. Reg. at 57,547.

4 4. Some objecting entities are willing to cover some (even if not all) contraceptives,  
5 and contraceptives are available from alternative sources, including from government programs  
6 for low-income women. *Id.* at 57,548. This is particularly relevant given research analyzing the  
7 effect of ACA implementation on contraceptive use, which concluded that: "The role that the  
8 contraceptive coverage guarantee played in impacting use of contraception at the national level  
9 remains unclear, as there was no significant increase in the use of methods that would have been  
10 covered under the ACA (most or moderately effective methods) during the most recent time period  
11 (2012-2014) excepting small increases in implant use," perhaps because "many women were able  
12 to access contraceptive methods at low or no cost through publicly funded family planning centers  
13 and Medicaid" prior to implementation of the ACA. AR at 00804231 (citing M.L. Kavanaugh et  
14 al., *Contraceptive Method Use in the United States: Trends and Characteristics Between 2008,*  
15 *2012 and 2014*, 97 *Contraception* 14, 14–21 (2018), AR 00804227).

16  
17  
18 In addition, although the Agencies had previously sought to provide contraceptive  
19 coverage to women "seamlessly," the Agencies determined that the government did not have a  
20 compelling interest in such seamlessness because of the disunity caused by the exemptions for  
21 grandfathered plans and for churches and their integrated auxiliaries, as well as the application of  
22 the accommodation to self-insured church plans. 83 Fed. Reg. 57,548.

23  
24 These considerations are more than sufficient to support the Agencies' conclusion that the  
25 mandate does not further a compelling government interest as applied to employers with religious  
26 objections. Although the existence of exceptions is by no means dispositive, "a law cannot be  
27

1 regarded as protecting an interest of the highest order . . . when it leaves appreciable damage to  
2 that supposedly vital interest unprohibited.” *Church of the Lukumi Babalu Aye, Inc. v. City of*  
3 *Hialeah*, 508 U.S. 520, 547 (1993) (cleaned up).

4 Plaintiffs’ attempts to dispute the Agencies’ reasoning fall flat. SJ. Mem. 26-29. Plaintiffs  
5 try to distinguish the Religious Exemption Rule from the exemption for churches and their  
6 integrated auxiliaries (which Plaintiffs apparently tolerate) by pointing to “our nation’s  
7 longstanding history of deferring to a house of worship’s decisions about its internal affairs.” SJ  
8 Mem. at 28 (citation omitted). But HRSA did not afford churches and their integrated auxiliaries  
9 an exemption from any of the other preventive services included in its guidelines. And of course,  
10 our nation also has a longstanding history of recognizing protections for religious objectors other  
11 than houses of worship, as seen in the passage of RFRA, which compels the Religious Exemption  
12 Rule at issue here. Plaintiffs also seek to discount the availability of contraception from other  
13 sources based on the fact that these programs may not be available to all women. SJ Mem. at 29.  
14 But empirical evidence in the record concluded that the implementation of the mandate was not  
15 accompanied by an uptick in contraceptive use in general or forms of contraception other than  
16 implants. Such empirical analysis would, of course, have reflected the actual availability of  
17 contraceptives from alternative sources.

18  
19  
20 In sum, Plaintiffs cite no case law supporting the proposition that they, and not the  
21 Agencies, are the arbiters of the *Government’s* interest, and, in any event, the Government is  
22 unaware of any case in which a court has held that the Government has a compelling interest when  
23 the Government itself has not asserted such an interest.

24  
25 **C. Alleged Third Party Harm Is Not a Reason to Neglect RFRA’s**  
26 **Requirements**

27 Plaintiffs argue erroneously in several places that the Rule will cause harm to third parties.

1 SJ Mem. 24-25, 30-32. That argument is erroneous because, as noted elsewhere, contraceptives  
 2 are available from other sources and evidence indicates that the mandate itself did not cause an  
 3 increase in the use of contraceptives. In any event, RFRA contains no separate limitation on  
 4 avoiding exemptions that may affect third-parties. Indeed, nearly all exemptions—even the  
 5 individual, judicially-imposed RFRA exemptions that Plaintiffs favor—may have some effect on  
 6 third parties. Here, the agencies reasonably concluded that application of the mandate to  
 7 employers with religious objections neither serves a compelling interest nor is narrowly tailored  
 8 to such an interests. That is all RFRA requires. *Cf. Benning v. Georgia*, 391 F.3d 1299, 1312-13  
 9 (11th Cir. 2004) (holding that the religious exemption in RLUIPA does not facially burden third  
 10 party interests unduly, because RLUIPA allows States to satisfy compelling interests). To the  
 11 extent Plaintiffs seek to reiterate their argument that the Rules violate the Establishment Clause<sup>12</sup>—  
 12 an argument which would equally apply to the existing exemption for churches and their integrated  
 13 auxiliaries, as well as to self-insured church plans that avail themselves of the accommodation—  
 14 those arguments fail for the reasons discussed in Argument § 4; the Rules simply do not “burden”  
 15 third parties by eliminating a government-imposed requirement that certain employers provide a  
 16 benefit to those third parties.

19 **D. RFRA Permits Agencies to Create Exemptions to Alleviate Substantial**  
 20 **Burdens on Religious Exercise**

21 Plaintiffs argue that RFRA permits only individual, judicially-created exemptions, SJ

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23 <sup>12</sup> Plaintiffs cite to language in *Hobby Lobby* stating that “in applying RFRA ‘courts must take  
 24 adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.’”  
 25 SJ. Mem. at 30 (quoting *Hobby Lobby*, 573 U.S. at 729 n.37). This language quotes *Cutter v.*  
 26 *Wilkinson*, 544 U.S. 709, 720 (2005), which relies on *Estate of Thornton v. Caldor, Inc.*, 472  
 27 U.S. 703 (1985), an Establishment Clause case pre-dating RFRA’s enactment. This language  
 reiterates the unremarkable proposition that, in alleviating substantial burdens under RFRA, the  
 Government may not violate the Establishment Clause.



1 Mem. at 32-33, and that the Agencies must therefore await a lawsuit before they bring their actions  
2 into compliance with the law. Yet, by its own text, RFRA applies to “the implementation of” “all  
3 Federal law,” 42 U.S.C. § 2000bb-3(a), which necessarily includes agency regulations and  
4 guidance. In addition, RFRA provides that the “Government shall not substantially burden a  
5 person’s exercise of religion” unless strict scrutiny is satisfied, *id.* § 2000bb-1(a)-(b). The plain  
6 text of the statute itself thus prohibits a federal agency from promulgating a regulation that it knows  
7 would impose such an unjustified burden.  
8

9 RFRA’s plain text thus authorizes agencies to take affirmative steps to eliminate substantial  
10 burdens on religious exercise and does not require that the Agencies await the inevitable lawsuit  
11 and judicial order to comply with RFRA. Moreover, if a RFRA violation could be cured only  
12 through a judicial proceeding, it would lead to perverse results: here, for example, the Agencies  
13 would not have been able to create the accommodation for employers that wish to use it, and  
14 instead would have been forced to provide even those employers an exemption when they invoked  
15 RFRA as “a claim or defense” against enforcement of the contraceptive-coverage mandate. *See*  
16 42 U.S.C. § 2000bb-1(c).  
17

18 Furthermore, although RFRA prohibits the government from substantially burdening a  
19 person’s religious exercise where doing so is not the least restrictive means of furthering a  
20 compelling interest—as is the case with the contraceptive-coverage mandate, per *Hobby Lobby*—  
21 RFRA does not prescribe the precise remedy by which the government must eliminate that burden.  
22 There may be a range of permissible approaches that the government may take to alleviate the  
23 substantial burden, and RFRA does not require the government to inch forward one quantum of  
24 exemption at a time—all the while defending against RFRA lawsuits by religious objectors—until  
25 it stumbles upon the most restrictive accommodation that withstands the objector’s RFRA  
26  
27

1 objections. This principle is aptly demonstrated by the history of religious exemptions to the  
2 contraceptive-coverage mandate.

3 In *Hobby Lobby*, the Supreme Court held that the contraceptive-coverage mandate,  
4 standing alone, “imposes a substantial burden” on objecting employers. 573 U.S. at 726. The  
5 Court further held that application of the mandate to objecting employers was not the least  
6 restrictive means of furthering any compelling governmental interest, because, at a minimum, the  
7 accommodation was a less restrictive alternative that could be extended to the objecting employers  
8 in that case. *See id.* at 727-33. Accordingly, the Agencies tried applying the accommodation to  
9 all objecting employers. But objections remained. The Supreme Court was expected to decide  
10 whether the objections to the accommodation were legally valid in *Zubik*. But the Court instead  
11 remanded the matter to allow the parties to try to find another accommodation; they could not.  
12 The Agencies could find no way to amend the accommodation to both account for employers’  
13 religious objections and provide seamless coverage to their employees. *See* FAQs About  
14 Affordable Care Act Implementation Part 36, at 4. After that decision, the Agencies reasonably  
15 decided to adopt the Religious Exemption Rule to satisfy their RFRA obligation to eliminate the  
16 substantial burden imposed by the mandate, because “many religious entities have objections to  
17 complying with the accommodation based on their sincerely held religious beliefs.” 82 Fed. Reg.  
18 at 47,806, 83 Fed. Reg. at 57,544-48. This was entirely in keeping with the *Hobby Lobby*  
19 decision—the Court did not decide whether the accommodation would satisfy RFRA for all  
20 religious claimants; nor did it suggest that the accommodation is the only permissible way for the  
21 government to comply with RFRA and the ACA, even assuming the existence of a compelling  
22 governmental interest.

23  
24  
25  
26 Nothing in RFRA compelled the Agencies to continue their unsuccessful efforts to find an  
27

1 accommodation that would satisfy all religious objectors or prohibited them from employing the  
2 more straightforward choice of an exemption—much like the existing and unchallenged exemption  
3 for churches. Indeed, if the Agencies had simply adopted an exemption from the outset—as they  
4 did for churches—no one could reasonably have argued that doing so was improper because the  
5 Agencies should have invented the accommodation instead. Neither RFRA nor the ACA compels  
6 a different result here based merely on path dependence.

7  
8 The Agencies’ choice to adopt an exemption in addition to the accommodation is  
9 particularly reasonable given the litigation over whether the accommodation violates RFRA. 82  
10 Fed. Reg. at 47,798; *see also Ricci v. DeStefano*, 557 U.S. 557, 585 (2009) (holding that an  
11 employer need only have a strong basis to believe that an employment practice violates Title VII’s  
12 disparate-impact ban in order to take certain types of remedial action that would otherwise violate  
13 Title VII’s disparate-treatment ban);<sup>13</sup> *cf. Walz v. Tax Comm’n of City of N.Y.*, 397 U.S. 664, 669  
14 (1970) (recognizing “room for play in the joints” when accommodating exercise of religion). Here,  
15 where the accommodation still imposed a substantial burden on some entities, the Agencies acted  
16 reasonably and permissibly in choosing to enact the Religious Exemption Rule rather than  
17 attempting to iterate a different version of the accommodation and proceed with decades of  
18 litigation over whether that updated accommodation sufficiently removed the substantial burden.

19  
20 Nor do the Agencies maintain that they are authorized to create any exemptions they want  
21 under RFRA. The Agencies’ exercise of their authority to shape the content and scope of any  
22 preventive-services guidelines is subject to “arbitrary and capricious” review under the APA, and  
23

24  
25 <sup>13</sup> Defendants seek to clarify that they do not argue that HHS is entitled to deference in  
26 interpreting RFRA, *see* Order, ECF No. 234, at 32, but instead argue that there is room for play  
27 in the joints such that there are multiple permissible approaches the government may take  
pursuant to RFRA to alleviate a substantial burden.

1 the Religious Exemption Rule at issue here is tailored because it applies only to employers with a  
 2 sincere religious objection to the mandate.<sup>14</sup>

### 3 **III. The Rules Are Not Arbitrary and Capricious**

4 Plaintiffs argue that the Exemption Rules are arbitrary and capricious for three reasons: (1)  
 5 Defendants have failed to provide a reasoned explanation for the promulgation of the Religious  
 6 and Moral Exemption Rules; (2) the Exemptions are not well tailored to the problem they are  
 7 intended to address; and (3) Defendants failed to meaningfully respond to comments concerning  
 8 the “Rules’ impacts.” SJ Mem. 37-51. These arguments fail.  
 9

#### 10 **A. Defendants Provided a Reasoned Explanation for the Promulgation of the Rules**

##### 11 1. The Rules Satisfy the *Fox* Standard and Are Consistent with the Evidence Before 12 the Agencies

13 Plaintiffs claim that the standard for an adequate explanation is particularly high in the  
 14 circumstances of this case because women have developed “serious reliance interests” related to  
 15 the availability of cost-free contraceptive coverage. SJ Mem. at 38-39 (quotations omitted).  
 16 Building from this premise, Plaintiffs contend that “Defendants’ Exemption Rules fail to provide  
 17 the requisite reasoned explanation, particularly given the lack of any material change in the  
 18 underlying factual and legal circumstances that supported their prior position.” *Id.* at 39.  
 19 Moreover, Plaintiffs contend that the Rules’ conclusion that the benefits of contraceptives are  
 20 “more uncertain” than previously recognized contradicts the fact that the “HRSA guidelines  
 21 continue to require coverage of the full range of FDA-approved contraceptive methods[,] [a]nd  
 22 [the fact that] HHS continues to inform women that birth control is generally safe, depending on  
 23

24  
 25 <sup>14</sup> Plaintiffs devote significant space to arguing that the accommodation is the “least restrictive  
 26 means” of furthering a compelling governmental interest. SJ Mem. at 26-34. But, as explained  
 27 above, the mandate does not further a compelling governmental interest as applied to employers  
 with religious objections, and thus the least-restrictive-means analysis is not relevant.

1 the type of birth control used and a woman's individual health." *Id.* at 40. They also complain  
2 that the Rules' conclusions regarding the benefits of contraceptives and of contraceptive coverage  
3 run counter to evidence before the Agencies in the rulemaking. *Id.* at 40-43.

4 Plaintiffs' scattershot arguments are unpersuasive. "The scope of review under the  
5 'arbitrary and capricious' standard is narrow." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State*  
6 *Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency generally need not demonstrate  
7 "that the reasons for the new policy are better than the reasons for the old one," but only that "the  
8 new policy is permissible under the statute, that there are good reasons for it, and that the agency  
9 believes it to be better." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). In  
10 situations where the "prior policy has engendered serious reliance interests that must be taken into  
11 account," an agency should provide a "reasoned explanation" for treating differently "facts and  
12 circumstances that underlay or were engendered by the prior policy." *Id.* at 516; *see also Encino*  
13 *Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

14  
15 Even assuming that the prior policy could have engendered reliance interests in the face of  
16 active litigation and repeated rulemaking efforts in this space, the Agencies did just that: The Final  
17 Rules contain voluminous explanations of the Agencies' previous position, their current position,  
18 the Agencies' recognition that their position had changed, discussions of both sides of the issue  
19 from public comments, and extensive reasoning for their conclusions in the Final Rules. *See, e.g.*,  
20 83 Fed. Reg. at 57,546–56. The Agencies did not ignore their prior findings or any reliance  
21 interests—over the course of four pages of the Federal Register, 83 Fed. Reg. at 57,552-56, the  
22 Agencies discuss the efficacy and health effects of contraceptive use as well as the effect, if any,  
23 the mandate had on contraceptive use. *See Fox Television*, 556 U.S. at 516 (rejecting argument  
24 that the FCC offered an inadequate explanation in an order by noting, in part, that "[t]he Remand  
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1 Order does, however, devote four full pages of small-type, single-spaced text . . . to explaining”  
2 the relevant conclusion). Specifically, with respect to any reliance interests, the Agencies  
3 concluded, after reviewing applicable studies and comments, that “it is not clear that merely  
4 expanding exemptions as done in these rules will have a significant effect on contraceptive use,”  
5 given that “there is conflicting evidence regarding whether the mandate alone, as distinct from  
6 birth control access more generally, has caused increased contraceptive use, reduced unintended  
7 pregnancies, or eliminated workplace disparities, where all other women’s preventive services  
8 were covered without cost sharing.” 83 Fed. Reg. at 57,556.  
9

10 Through this discussion in the Rules, the Agencies demonstrated why, in their judgment,  
11 the policy interests in favor of expanding the exemptions outweigh the interests in leaving the  
12 contraceptive-coverage mandate unchanged: the evidence on the benefits of contraceptives and  
13 the mandate is more mixed—and the religious and conscientious objections to complying with the  
14 mandate more substantial—than the Agencies previously acknowledged. To that end, the Ninth  
15 Circuit has recognized that—contrary to Plaintiffs’ suggestions, SJ Mem. at 39—changed factual  
16 circumstances are not a prerequisite to policy change. In *Village of Kake v. U.S. Department of*  
17 *Agriculture*, the Ninth Circuit concluded that an agency was entitled to “give more weight to  
18 socioeconomic concerns than it [previously] had [two years earlier], even on precisely the same  
19 record.” 795 F.3d 956, 968 (9th Cir. 2015) (en banc). Just so here. The record before the Agencies  
20 justified a different balancing of “the various policy interests at stake.” 83 Fed. Reg. at 57,556. Of  
21 course, the uncertainty of the net benefits of contraceptives is just one reason for the Agencies’  
22 conclusion that there is no compelling interest in requiring those with conscience objections to  
23 provide contraceptive coverage; the Rules provide other independent and sufficient reasons for  
24 reaching that conclusion. *Id.* at 57,546-48.  
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1       What is more, there is nothing inconsistent about the Agencies promulgating the Rules  
2 while at the same time recognizing that contraceptives can be beneficial. The Rules do not reach  
3 conclusions about whether there are *ever* any benefits to contraceptive use. Rather, they address  
4 the proper *balance* between conscience objections and the contraceptive coverage requirement.  
5 83 Fed. Reg. at 57,556. Thus, it is entirely reasonable for the Agencies to recognize that  
6 contraceptives—and contraceptive coverage—provide some benefits, while at the same time  
7 concluding that the net benefits are less certain than previously acknowledged and do not justify  
8 demanding that those with sincere conscience objections be required to provide contraceptive  
9 coverage.  
10

11       Plaintiffs' arguments that the Agencies did not adequately address comments from medical  
12 groups regarding the benefits of contraceptives and contraceptive coverage are similarly  
13 misplaced. At the outset, it is important to acknowledge the appropriate standard for evaluating  
14 such arguments:  
15

16             A court generally must be at its most deferential when reviewing  
17 scientific judgments and technical analyses within the agency's  
18 expertise. We may not impose ourselves as a panel of scientists that  
19 instructs the agency, chooses among scientific studies, and orders  
20 the agency to explain every possible scientific uncertainty. And  
21 when specialists express conflicting views, an agency must have  
22 discretion to rely on the reasonable opinions of its own qualified  
23 experts even if, as an original matter, a court might find contrary  
24 views more persuasive.

25       *Tri-Valley CAREs v. U.S. Dep't of Energy*, 671 F.3d 1113, 1124 (9th Cir. 2012) (cleaned up). This  
26 deferential standard derails Plaintiffs' efforts to have this Court second-guess the Agencies'  
27 handling of comments regarding medical and health policy issues.

28       Plaintiffs' first science-focused argument is that the medical evidence before the Agencies  
undercuts the conclusion that the benefits of contraceptives were more uncertain than previously

1 recognized. SJ Mem. at 39-41. But the efficacy of contraceptives is a medical issue, which lies  
 2 well within the ambit of HHS's scientific and technical expertise. *See, e.g., Styrene Info. &*  
 3 *Research Ctr., Inc. v. Sebelius*, 944 F. Supp. 2d 71, 87 (D.D.C. 2013) (explaining that HHS's  
 4 scientific judgments are owed deference); *Tozzi v. U.S. Dep't of Health & Human Servs.*, 180 F.  
 5 Supp. 2d 1, 6 (D.D.C. 2000), *aff'd*, 271 F.3d 301 (D.C. Cir. 2001) (noting, in the context of a  
 6 challenge to HHS's scientific judgment about the classification of a carcinogen, that "as an agency  
 7 charged with making scientific judgments, [it] is due great deference"). And the Agencies cite  
 8 ample medical evidence in the Rules, *see, e.g.*, 83 Fed. Reg. at 57,552-53 nn.28-34, drawn from  
 9 the Administrative Record,<sup>15</sup> to support their conclusion that the benefits of contraceptives are  
 10 more uncertain than previously recognized, *see, e.g.*, 78 Fed. Reg. at 39,872 (discussing the  
 11 benefits of contraceptives). Indeed, in support of the conclusion that the benefits of contraceptives  
 12 are more uncertain than previously acknowledged, the Rules cite over 20 studies from well-  
 13 established peer-reviewed medical journals such as the New England Journal of Medicine, The  
 14 Lancet, and the Journal of the American Medical Association. 83 Fed. Reg. at 57,552-53 nn.28-  
 15 34. Plaintiffs, with their own favored studies in hand, disagree with the Agencies' judgment on  
 16 this score, but like the Court, they "may not impose [themselves] as a panel of scientists that  
 17 instructs the agency [and] chooses among scientific studies." *Tri-Valley CAREs*, 671 F.3d at 1124.

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23 <sup>15</sup> *See, e.g.* AR at 00803140-00803154 (Y. Vinogradova et al., "Use of Combined Oral  
 24 Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the  
 25 QResearch and CPRD Databases," 350 *Brit. Med. J.* h2135 (2015)); AR at 00803775-  
 26 00803784)( Ø. Lidegaard et al., "Thrombotic Stroke and Myocardial Infarction with Hormonal  
 27 Contraception, 366 *N. Engl. J. Med.* 2257 (2012)); AR at 00803785-00803791 (M. Vessey et al.,  
 "Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking," 362 *Lancet* 185  
 (2003)); and AR at 00803810-00803816 (L.A. Gillum et al., "Ischemic stroke risk with oral  
 contraceptives: A meta analysis," 284 *JAMA* 72, 72-78 (2000)).



Plaintiffs also insist that the Agency disregarded evidence regarding the benefits of the contraceptive-coverage mandate. SJ Mem. at 41-43. That is incorrect. Plaintiffs assert that the contraceptive-coverage mandate has increased contraceptive use and reduce unintended pregnancies, and that evidence before the Agencies demonstrated as much. *Id.* But the Agencies reviewed the evidence submitted during the comment period and reached a different conclusion. They determined that “[t]here is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women’s preventive services were covered without cost sharing.” 83 Fed. Reg. at 57,556. In reaching this conclusion, the Agencies relied on evidence submitted during the comment period, including studies by the Guttmacher Institute, to support this conclusion. *Id.* at 57,555 nn.51-53. This issue also falls within the realm of HHS’s expertise in health policy, and under the APA, HHS’s conclusions are entitled to deference. “[W]hen specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court [or plaintiffs] might find contrary views more persuasive.”<sup>16</sup> *Tri-Valley CAREs*, 671 F.3d at 1124.

## 2. The Agencies Did Not Ignore Plaintiffs’ Purported Reasonable Alternative

Plaintiffs contend that the Agencies violated the APA because they did not adequately consider an alternative course to the issuance of the Rules, namely, “why any purported uncertainty regarding health risks [of contraceptives] cannot be adequately addressed through a woman’s consultation with her personal physician.” SJ Mem. at 41. Under the APA, however, an agency

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<sup>16</sup> The Agencies also adequately responded to comments about the efficacy of contraceptives and the contraceptive-coverage mandate, for the reasons described above.

1 need “consider only significant and viable” alternatives. *Nat’l Shooting Sports Found., Inc. v.*  
2 *Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (quotations omitted). Plaintiffs’ physician-consultation  
3 suggestion is not a viable alternative because it would not satisfy or mitigate the conscience  
4 objections to providing contraceptive coverage.

5           3. The Agencies Adequately Considered the Costs of the Rules

6           Plaintiffs initially argue that Defendants’ alleged “[f]ailure to account for the actual costs  
7 of the Exemption Rules renders them arbitrary and capricious.” SJ Mem. at 43. But the Agencies  
8 did not ignore the costs of the Rules. Rather, the Religious Exemption Rule notes that it could  
9 result in over \$67 million in costs being transferred (depending on the number of entities that  
10 invoke the exemption), 83 Fed. Reg. at 57,581, while the Moral Exemption Rule notes that it could  
11 result in up to \$8,760 in transfer costs (with the same caveat). Plaintiffs eventually acknowledge  
12 these facts. SJ Mem. at 43. They then, however, move the goal posts and fault the Rules for failing  
13 to “explicitly detail who will bear such [future] costs.” *Id.* But Plaintiffs cite no cases holding  
14 that, to comply with the APA, an agency must “explicitly detail” who will bear various future  
15 costs. Nor could they, for the APA demands reasoned decision making, not omniscience. *CHW*  
16 *W. Bay v. Thompson*, 246 F.3d 1218, 1223 (9th Cir. 2001) (explaining that “arbitrary and  
17 capricious review under the APA focuses on the reasonableness of an agency’s decision-making  
18 processes”) (quotation marks omitted); *cf. O’Bryant v. Idaho Dep’t of Health & Welfare*, 841 F.  
19 Supp. 991, 998 (D. Idaho 1993) (concluding that “nothing in the APA ‘requires the Secretary to  
20 engage in the virtually impossible task of listing every type of benefit which is not excluded from  
21 income’) (quotation marks omitted). The Agencies could not detail who would bear the costs of  
22 employers or schools invoking the exemption, or how much they would bear. The answers to  
23 those questions would depend on facts that were not only unknown, but, practically speaking,  
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1 unknowable at the time the Rules were promulgated, such as how many entities would invoke the  
 2 exemptions, whether any affected woman would receive coverage under a spouse's plan or  
 3 parent's plan, whether a woman would turn to—and qualify for—state programs, whether she  
 4 would obtain contraceptives through a clinic, and so on.

#### 5 4. The Rules Accord with Congressional Intent

6 Next, Plaintiffs contend that the Agencies violated the APA “by independently . . .  
 7 concluding that some uncertainties with respect to the efficacy and safety of contraceptives exist”  
 8 because Congress identified “HRSA as the arbiter of safe and efficacious women’s preventive  
 9 care” and charged HRSA with “promulgating guidelines that define preventive services.” SJ Mem.  
 10 at 44.  
 11

12 This argument is flawed. The ACA states, in relevant part, that “[a] group health plan and  
 13 a health insurance issuer offering group or individual health insurance coverage shall” cover “such  
 14 additional preventive care and screenings not described in paragraph (1) as provided for in  
 15 comprehensive guidelines supported by the Health Resources and Services Administration for  
 16 purposes of this paragraph.” 42 U.S.C. § 300gg-13(a)(4). HRSA is a component of HHS. *See* 47  
 17 Fed. Reg. at 38,409 (“Part H of the Statement of Organization, Functions and Delegations of  
 18 Authority of the Department of Health and Human Services is amended to . . . establish a new  
 19 Chapter HB (Health Resources and Services Administration) which replaces Chapters HR [Health  
 20 Resources Administration] and HS [Health Services Administration] in their entirety.”); HHS  
 21 Statement of Organization, Functions, and Delegations of Authority, Part H, § HB-00, 47 Fed.  
 22 Reg. at 38,409-02 (“HRSA is directed by an Administrator who is responsible to the Assistant  
 23 Secretary for Health”). HHS, and the other Defendant agencies, engaged in notice and comment  
 24 rulemaking to best determine how to address conscience objections, and, by extension, to what  
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1 extent contraceptive coverage should be “provided for” in HRSA’s guidelines. *See* 83 Fed Reg.  
 2 at 57,540; 83 Fed. Reg. at 57,592-57,593. Indeed, HRSA modified the “comprehensive  
 3 guidelines” to reflect the content of the Rules. *See* HRSA, Women’s Preventive Service  
 4 Guidelines, at <https://www.hrsa.gov/womens-guidelines/index.html>.

5 Thus, to the extent Plaintiffs are raising a technical objection that the Guidelines—and not  
 6 the Rules—control the scope of the required coverage, that objection fails because, among other  
 7 reasons, the Guidelines have been amended to incorporate the exemptions recognized by the Rules.  
 8 *Id.* And to the extent Plaintiffs are raising a more fundamental objection that HRSA could not be  
 9 guided by the Secretary of HHS in issuing the guidelines, that argument fails because HRSA is a  
 10 component of HHS under the Secretary’s control. The ACA did not change that fundamental fact  
 11 of agency structure *sub silentio* by tasking HRSA with certain duties in the implementation of the  
 12 APA.<sup>17</sup> *See Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001) (“Congress, we have held,  
 13 does not alter the fundamental details of a regulatory scheme in vague terms or ancillary  
 14 provisions—it does not, one might say, hide elephants in mouseholes.”).

### 17 **B. The Exemptions Are Tailored to the Problem They Are Intended to Address**

18 According to Plaintiffs, “[t]he serious lack of alignment between the purported problems  
 19 Defendants cited as a basis for the Exemption Rules and the scope of the new policy they seek to  
 20 implement demonstrates that the Rules are arbitrary and capricious.” SJ Mem. at 45 (quotation  
 21 marks omitted). Plaintiffs are wrong again, because they misidentify the “problems” that the Rules  
 22 were designed to address. They maintain that the Rules are not adequately tailored to address  
 23 concerns about the safety of contraceptives, contraceptive access and teen pregnancy, or the  
 24

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26 <sup>17</sup> To the extent Plaintiffs’ argument here is a recycled version of their argument that the ACA  
 27 does not afford the Agencies the discretion to create or expand the exemptions, Defendants  
 address it in Argument § 1.A above.

1 tailoring of the contraceptive-coverage mandate. *Id.* at 44-45. But these are not the problems that  
2 the Rules were intended to address. The Rules were intended to address religious and moral  
3 objections to the provision of contraceptive coverage. *See* 83 Fed. Reg. at 57,540; 83 Fed. Reg. at  
4 57,592-93. The matters that Plaintiffs identify as the “purported problems” to be solved by the  
5 Rules are, in fact, policy issues that the Agencies considered in determining how best to address  
6 the conscience objections to the provision of contraceptive coverage. *Id.* at 57,547-57,548, 57,552-  
7 57,556. An example illustrates the difference. If a state were considering what the maximum  
8 speed limit should be on its highways, then it might consider what percentage of the cars that use  
9 the road have certain advanced safety features, as a higher percentage would auger in favor of a  
10 higher speed limit. Consideration of that fact does not transform the problem – about what the  
11 speed limit should be – into a different one – how can the number of cars with advanced safety  
12 features be increased. The same reasoning applies here.

14 Plaintiffs embellish their argument by announcing that “the Rules are a solution in search  
15 of a problem.” SJ Mem. at 45. Dozens of cases and years of litigation, including several stops in  
16 the Supreme Court, say otherwise: Determining how best to balance conscience objections with  
17 the provision of contraceptive coverage is a real “problem,” not a figment of the Agencies’  
18 collective imaginations. And Plaintiffs’ supporting arguments do not fare any better. They assail  
19 the Agencies for extending the Religious Exemption Rule to publicly traded companies, even  
20 though the Agencies have stated they are not aware of any publicly traded entities that have  
21 publicly objected to providing contraceptive coverage based on a religious belief (83 Fed. Reg. at  
22 57,626). SJ Mem. at 46. But there is nothing “arbitrary or capricious” about including publicly  
23 traded entities within the scope of the Religious Exemption Rule. For one thing, RFRA applies to  
24 publicly traded entities, 83 Fed. Reg. at 57,626, *see Hobby Lobby*, 573 U.S. at 707–08 (discussing  
25 publicly traded entities, 83 Fed. Reg. at 57,626, *see Hobby Lobby*, 573 U.S. at 707–08 (discussing  
26 publicly traded entities, 83 Fed. Reg. at 57,626, *see Hobby Lobby*, 573 U.S. at 707–08 (discussing  
27 publicly traded entities, 83 Fed. Reg. at 57,626, *see Hobby Lobby*, 573 U.S. at 707–08 (discussing

the definition of “person” in RFRA), and for another, the invocation of the Religious Exemption by a publicly traded entity is not a logical or legal impossibility. In any case, if there is no publicly traded entity that has invoked the religious exemption, then the extension of the exemption to publicly traded companies has not caused any harm to Plaintiffs. (And if a publicly traded entity does properly invoke the exemption, then the Exemption could not be said to be unnecessarily broad.) Plaintiffs lodge a similarly meritless objection to the Moral Exemption Rule, arguing that the Moral Exemption Rule “cite[s] only three employers” to justify its existence. SJ Mem. at 46. But Plaintiffs (of course) identify no case holding that the APA requires that a rule be expected to affect a minimum number of entities before it can be issued—and, in any case, more entities may invoke the Rule in the future.

Finally, Plaintiffs argue that the Final Rules are unnecessary because “Defendants have stipulated to injunctions barring them from enforcing [the] contraceptive-coverage requirement against several employers, including ‘open-ended’ injunctions that allow additional employers to join.” SJ Mem. at 46. But if Plaintiffs think that Rules will not have a real-world effect, then the real problem is with Plaintiffs’ standing, not the reasonableness of the Rules. In any case, the Agencies do not believe that the injunctions protect—or will protect—all those with conscience objections, and Plaintiffs presumably agree, given that they have brought this suit and insist that they have standing to do so.

**c. Defendants Appropriately Responded to Comments About the Effects of Unintended Pregnancy and the Impact of the Rules on Victims of Domestic Violence**

Plaintiffs argue that the Rules are arbitrary and capricious because the Agencies did not “meaningfully acknowledge, engage, and [ ] respond to,” SJ Mem. at 50, comments regarding the “significant burdens associated with unintended pregnancies,” *id.* at 48. They also insist that the

Rules do not address the effect of the Rules on women who are victims of domestic violence. *Id.* at 50-51. These arguments are incorrect: The Agencies acknowledged and fulsomely responded to the comments regarding the burdens of unintended pregnancies and any connection to “societal inequality.” 83 Fed. Reg. at 57,548, 57,549-50. The Agencies explained that the Rules would not be imposing the burdens of any unintended pregnancies or creating societal inequality: “These rules simply relieve part of that governmental burden [of providing contraceptive coverage]. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed.” *Id.* at 57,549. They also noted that there is evidence that the contraceptive-coverage mandate did not affect contraceptive use and that, in any case, the scope of these exemptions is limited to entities with sincere religious and moral objections. *Id.* at 57,550. That Plaintiffs do not agree with these responses does not render them nonexistent.

#### IV. The Rules Comply with the Establishment Clause

Defendants have previously explained that the Rules are consistent with the Establishment Clause. *See* Defs.’ Opp. to Pls.’ Mot. for Prelim. Inj., ECF No. 51, at 29-32. As the Supreme Court has repeatedly held, “there is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.” *Cutter*, 544 U.S. at 713 (citation and internal punctuation omitted). The Rules serve the legitimate secular purpose of alleviating significant governmental interference with the exercise of religion. Additionally, the Rules neither promote nor subsidize any religious message or belief; rather, they allow entities and individuals with objections to contraception based on religious beliefs and moral convictions to practice those beliefs and convictions as they otherwise would in the absence of state-imposed regulations.

1 Finally, by reducing government interference with religious exercise, the Rules achieve a more  
2 complete separation of church and state, rather than entangling them.

3 Plaintiffs incorrectly contend that the Rules are inconsistent with the Establishment Clause  
4 because they unduly burden third parties. SJ Mem. at 33-55; *see also* Amicus Br. of Church-State  
5 Scholars at 2-6, ECF No. 325; Amici Br. of Religious & Civil Rights Organizations at 5-12, ECF  
6 No. 337-1. As previously explained, the Agencies expressly determined that application of the  
7 mandate to objecting entities neither serves a compelling interest nor is narrowly tailored to any  
8 such interest. *See* 83 Fed. Reg. at 57,546-48. This conclusion precludes any finding that the  
9 Religious Exemption Rule exceeds the agencies' authority under RFRA by unduly burdening the  
10 interests of third parties. *Cf. Benning*, 391 F.3d at 1312-13 (holding that RLUIPA's religious  
11 exemption does not facially burden third-party interests unduly, because RLUIPA allows States to  
12 satisfy compelling interests). Furthermore, as the Agencies reasonably concluded, the burden the  
13 mandate imposes on the small number of objecting employers is greater than previously thought,  
14 and outweighs the burden on women who might lose contraceptive coverage. *See* 83 Fed. Reg. at  
15 57,545-48.  
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18 Moreover, Plaintiffs' characterization of the loss of compelled contraceptive coverage as a  
19 governmental burden rests on the "incorrect presumption" that "the government has an obligation  
20 to force private parties to benefit those third parties and that the third parties have a right to those  
21 benefits." *Id.* at 57,549. "If some third parties do not receive contraceptive coverage from private  
22 parties who the government chose not to coerce [into providing such coverage], that result exists  
23 in the absence of governmental action—it is not a result the government has imposed." *Id.* Before  
24 the mandate, women had no entitlement to contraceptive coverage without cost-sharing. If the  
25 same agencies that created and enforce the contraceptive mandate also create a limited exemption  
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1 to accommodate sincere religious objections, the women affected are not “burdened” in any  
2 meaningful sense, because they are no worse off than before the Agencies chose to act in the first  
3 place.

4 This conclusion is supported by *Corporation of the Presiding Bishop of the Church of Jesus*  
5 *Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987), which held that Title VII’s religious  
6 exemption to the prohibition against religious discrimination in employment was consistent with  
7 the Establishment Clause even though the result was to affirm the employer’s right to terminate  
8 the plaintiff’s employment. While the plaintiff was “[u]ndoubtedly” adversely affected, the Court  
9 noted, “it was the Church[,] . . . not the Government, who put him to the choice of changing his  
10 religious practices or losing his job.” *Id.* at 337 n.15. Rather than burdening the Church’s  
11 employees, the exemption simply left them where they were before Title VII’s general prohibition  
12 and exemption were enacted. *See id.* (noting that the plaintiff employee “was not legally  
13 obligated” to take the steps necessary to save his job, and that his discharge “was not required by  
14 statute”). The same reasoning applies here, and a similar result follows. Any adverse effects result  
15 from a decision by private employers, not the government; and the burden is much less than the  
16 loss of a job, as it is merely the loss of subsidized contraceptive coverage by an employer with  
17 sincerely-held religious or moral objections to providing such coverage. As Defendants have  
18 explained previously, contrary reasoning would invalidate the church exemption.<sup>18</sup>  
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22 <sup>18</sup> The attempt by Amici Religious and Civil Rights Organizations to distinguish *Amos*—  
23 and the Supreme Court’s later decision in *Hosanna-Tabor Evangelical Lutheran Church &*  
24 *School v. EEOC*, 565 U.S. 171 (2012)— is not persuasive. ECF 337-1 at 6. Contrary to Amici’s  
25 assertion, *Amos* is not inapposite because it concerned the institutional autonomy of religious  
26 congregations and religious not-for-profits to control their own leadership and membership.  
27 That cramped view of the permissibility of accommodating religious beliefs finds no support in  
28 *Amos*, which spoke broadly of the government’s authority to alleviate governmental interference  
with the ability of religious organizations to “define and carry out their religious missions.” 483  
U.S. at 335. That is precisely what the religious exemption here seeks to accomplish. *See also*

Plaintiffs and Amici also incorrectly suggest that the religious exemption constitutes the kind of “absolute and unqualified” exception the Supreme Court held unconstitutional in *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985). SJ Mem. at 52, 54; *see also* Amicus Br. of Church-State Scholars at 13-17; Amici Br. of Religious & Civil Rights Organizations at 5-7. The statute at issue in *Caldor* did not lift any governmental burden on religion, but instead intruded on private relationships by imposing on employers an “absolute duty” to allow employees to be excused from work on “the Sabbath [day] the employee unilaterally designate[d].” *Caldor*, 472 U.S. at 709. By contrast, the Rules neither compel nor encourage any action on a private employer’s part. Instead, they *lift* a burden on the exercise of religion—that employers are required to provide contraceptive coverage to their employees regardless of their contrary religious beliefs or moral convictions—that the government itself imposed, *see Amos*, 483 U.S. at 338. Moreover, the government has done so only after determining that the substantial burden on religious exercise is not narrowly tailored to achieve any compelling interest. The lifting of a *government-imposed* burden on religious exercise is permitted under the accommodation doctrine referenced in *Amos*. *See Tex. Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality opinion). In addition, *Caldor* involved government interference with private contracts. By contrast, the Rules involve a benefit that the government need not have required at all.<sup>19</sup>

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*Cutter*, 544 U.S. at 720 (finding RLUIPA’s institutionalized-persons provision “compatible with the Establishment Clause because it alleviates exceptional government-created burdens on private religious exercise” and citing *Amos*, 483 U.S. at 349, for the proposition that “removal of government-imposed burdens on religious exercise is more likely to be perceived as an accommodation of the exercise of religion rather than as a Government endorsement of religion”) (internal punctuation omitted)).

<sup>19</sup> Amici Religious and Civil Rights Organizations misplace their reliance on Free Exercise jurisprudence. Amici Br. of Religious & Civil Rights Organizations, ECF No. 337-1, at 5-6. Contrary to Amici’s characterization, the reason that the Supreme Court in *United States v. Lee*, 455 U.S. 252 (1982), rejected an Amish employer’s request for an exemption from paying social security taxes was because “the ‘tax system could not function if denominations were allowed to

1 Additionally, Amici is simply incorrect that the Rules contain no oversight mechanisms  
 2 aimed at preventing insincere assertions of religious belief. As the Agencies explained, “the  
 3 mandate is enforceable through various [statutory] mechanisms” and “[e]ntities that insincerely or  
 4 otherwise improperly operate as if they are exempt would do so at the risk of enforcement and  
 5 accountability under such mechanisms.” 83 Fed. Reg. at 57,615.

6 The Rules also “do[] not single out a particular class of [religious observers] for favorable  
 7 treatment and thereby have the effect of implicitly endorsing a particular religious belief.” *Hobbie*  
 8 *v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. at 136, 145 n.11 (1987). Rather, the fact that  
 9 the Rules apply to entities and individuals with secular, non-religious moral beliefs regarding the  
 10 provision of contraception confirms that the Rules possess a secular purpose. And similar to the  
 11 religious accommodation the Ninth Circuit upheld in *Kong v. Scully*, 341 F.3d 1132 (9th Cir.  
 12 2003), which protected all who are religiously motivated to seek health care in ‘religious  
 13 nonmedical health care institutions,’ the Religious Exemption Rule provides a sect-neutral  
 14 exception to the mandate. Moreover, Amici Religious and Civil Rights Organizations cite no  
 15 authority supporting their assertion that the mere fact that the religious exemption may apply to  
 16 publicly-traded companies but the moral exemption does not, Amici Br. of Religious & Civil  
 17 Rights Organizations, ECF No. 337-1, at 19, is tantamount to an Establishment Clause violation.

18 The Agencies explained in the interim moral-exemption rule that “the combined lack of any  
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 23 challenge the tax system because tax payments were spent in a manner that violates their  
 24 religious belief,” and not because the request allegedly burdened third parties. *Gonzales v. O*  
 25 *Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 435 (2006) (quoting *Lee*, 455 U.S.  
 26 at 260). Similarly, the reason that the Sunday closing law in *Braunfeld v. Brown*, 366 U.S. 599  
 27 (1961), could be applied constitutionally to Jewish business owners was in large part because of  
 28 the “strong state interest in providing one uniform day of rest for all workers,” which meant that  
 the requested exemption “would have rendered the entire statutory scheme unworkable.”  
*Sherbert v. Verner*, 374 U.S. 398 (1963). No such important state interests in consistency of  
 administration are present here.

lawsuits challenging the mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity” had led them “to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so.” 82 Fed. Reg. at 47,851. After considering such comments, the Agencies reasonably decided not to include publicly-traded entities in the moral exemption. Amici are mistaken that any impermissible religious purpose motivated the Agencies in reaching this conclusion.

Finally, Amici’s bold argument that the moral exemption itself violates the Establishment Clause, Opp. at 19-20, rests on flawed logic. Accepting Amici’s argument would require the Court to agree with the following syllogism: (1) The moral exemption applies to convictions that are deeply and sincerely held. (2) Courts have recognized that such moral beliefs can play a role in a nonreligious person’s life that is akin to a religion. (3) Therefore, relieving a government-imposed burden on deeply-held moral beliefs violates the Establishment Clause. But the conclusion does not follow from the stated premises; moreover, Amici cite no case in which a court found an Establishment Clause violation based on an attempt to relieve burdens on non-religious moral beliefs.<sup>20</sup>

#### V. The Rules Are Consistent with the Equal Protection Clause

The Rules are also consistent with principles of equal protection. When faced with a claim of discrimination on the basis of sex, courts assess (i) whether the classification is facially based upon sex and, if not, (ii) whether there are other factors—such as the purpose of the law or the existence of a disparate impact—that demonstrate an invidious intent to discriminate on the

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<sup>20</sup> *United States v. Ward*, 989 F.2d 1015 (9th Cir. 1992), does not assist Amici because that case does not even mention the Establishment Clause.

1 basis of sex. *See Personnel Adm’r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979). With regard to  
2 “this second inquiry, impact provides an important starting point, but purposeful discrimination  
3 is the condition that offends the Constitution.” *Id.* (citations omitted). Sex-based distinctions are  
4 subject to intermediate scrutiny, meaning that the distinction must be substantially related to an  
5 important governmental interest. *Wengler v. Druggists Mut. Ins. Co.*, 446 U.S. 142, 150 (1980).  
6 All other distinctions that do not target a protected class or burden a fundamental right are  
7 subject to rational-basis review. *Heller v. Doe*, 509 U.S. 312, 319–20 (1993). Under this  
8 standard, “a classification must be upheld ... if there is any reasonably conceivable state of facts  
9 that could provide a rational basis for the classification.” *Id.* at 320 (citation omitted).

11 Plaintiffs contend that the Rules discriminate against women because they “explicitly target  
12 contraceptive coverage.” SJ Mem. at 54. In fact, the Rules do not discriminate against women on  
13 the basis of sex, facially or otherwise. The Rules and HRSA Guidelines generally require coverage  
14 for female contraceptives, while providing an exemption for those with religious and conscience  
15 objections. The Rules and Guidelines do not require any coverage of male contraceptives. *See* 78  
16 Fed. Reg. at 8,458 n.3. Nor could they: The statutory provision requiring coverage for additional  
17 preventive services supported by HRSA pertains only to such services for “women.” 42 U.S.C. §  
18 300gg-13(a)(4). Thus, the Rules do not treat men more favorably, and any sex-based distinctions  
19 flow from the statute requiring preventive services for women only, not from the Agencies  
20 improperly “singl[ing] out” women. SJ Mem. at 54. Moreover, any distinctions in coverage  
21 among women are not premised on sex, but on the existence of a religious or moral objection on  
22 the part of an employer to facilitating the provision of contraceptives.

25 Notably, Plaintiffs fail to cite any authority suggesting that declining to require the  
26 subsidization of contraception constitutes a sex-based equal protection violation. *Caban v.*

1 *Mohammed*, 441 U.S. 380 (1979), involved a distinction between unwed mothers and unwed  
2 fathers in state domestic-relations law, not a subsidization. *Arce v. Douglas*, 793 F.3d 968 (9th  
3 Cir. 2015), did not even discuss sex-based discrimination; instead, it concerned claims of racial  
4 and ethnic discrimination. Moreover, neither *International Union, United Automobile, Aerospace,*  
5 *and Agricultural Implement Workers of America, UAW v. Johnson Controls, Inc.*, 499 U.S. 187  
6 (1991), nor the 2000 EEOC decision cited by Plaintiffs involve alleged constitutional violations;  
7 instead, both were exclusively concerned with statutory claims (Title VII) not presented here. That  
8 distinction matters because unlike Title VII, “[t]he equal protection component of the Fifth  
9 Amendment prohibits only purposeful discrimination” rather than disparate impact. *Harris*, 448  
10 U.S. at 323 n.26 (citing *Washington v. Davis*, 446 U.S. 229 (1976)). Distilled to its essence,  
11 Plaintiffs’ claim is that despite the fact that the Rules do not draw any sex-based distinction, an  
12 exemption to subsidizing contraception disparately affects women. That claim is meritless because  
13 it does not state a cognizable equal protection claim on the basis of sex.  
14

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16 Because the Rules do not create sex-based distinctions, they are subject to rational basis  
17 review. They satisfy this “lowest level of scrutiny,” *United States v. Dumas*, 64 F.3d 1427, 1429  
18 (9th Cir. 1995), because they are rationally related to legitimate government interests, *Lyng v. Int’l*  
19 *Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW*, 485 U.S. 360, 370  
20 (1988). The Religious Exemption Rule accommodates religion by “provid[ing] conscience  
21 protections for individuals and entities with sincerely held religious beliefs in certain health care  
22 contexts.” 82 Fed. Reg. at 47,793. The accommodation of religious beliefs is an important  
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1 government interest, as the Supreme Court recognized in *Cutter*, 544 U.S. at 724-25. For the  
 2 same reasons, the Rule would satisfy intermediate scrutiny.<sup>21</sup>

3 The Moral Exemption Rule also has a rational basis (and satisfies intermediate scrutiny).  
 4 It is designed to protect “sincerely held moral convictions” by exempting those with such  
 5 convictions from facilitating the provision of contraceptive services. 82 Fed. Reg. at 47,839. The  
 6 government may permissibly accommodate deeply held moral convictions and has furthered this  
 7 important interest in a variety of contexts since the founding. *See Welsh v. United States*, 398 U.S.  
 8 333 (1970); *United States v. Seeger*, 380 U.S. 163 (1965); *Doe v. Bolton*, 410 U.S. 179 (1973); 82  
 9 Fed. Reg. at 47,838 n.1. Indeed, some of the Plaintiff States protect moral beliefs in healthcare.  
 10 *See, e.g.*, Cal. Health & Safety Code § 123420; Md. Code Ann., Health – Gen. § 20-214. Plaintiffs  
 11 cite no authority suggesting that the importance of this or any other long-recognized government  
 12 interest depends on the number of entities that have expressed interest in an accommodation  
 13 intended to protect that interest. SJ Mem. at 55-56.

#### 16 **VI. The Rules Were Properly Promulgated After a Period of Notice and Comment** 17 **Under the APA**

18 Plaintiffs claim that the Agencies’ use of a post-promulgation comment period after issuing  
 19 the IFRs renders the Rules invalid under the APA. *See* SJ Mem. at 56–58. The Agencies maintain  
 20 that they had independent statutory authority to issue the IFRs, and had good cause to do so as  
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23 <sup>21</sup> Plaintiffs contend that if (contrary to fact) intermediate scrutiny applied, the means employed  
 24 by the Rules do not substantially relate to the government’s important interests in  
 25 accommodating sincerely-held religious and moral convictions. SJ Mem. at 56. But the Rules  
 26 leave the mandate in place for most applicable entities, and the accommodation, by itself, was  
 27 not satisfactory because it imposed a substantial burden on the exercise of religion of certain  
 entities. *See* 82 Fed. Reg. at 47,800. Thus, Plaintiffs should not be heard to contend that the  
 Rules are “broader than necessary,” SJ Mem. at 56, when Plaintiffs themselves fail to present an  
 adequate alternative solution for accommodating religious and moral convictions.



1 well.<sup>22</sup> See ECF No. 51 at 14-18 (arguing in favor of independent statutory authority to issue the  
2 IFRs, and in favor of the Agencies' determination of good cause). Accordingly, taking post-  
3 promulgation comments on the IFRs was proper. But even if, as this Court previously concluded,  
4 the IFRs violated the APA's procedural requirements, the Rules now at issue fully comply with  
5 the APA. What were post-promulgation comments with respect to the enjoined IFRs are now pre-  
6 promulgation comments with respect to the Rules. As such, the Agencies have now provided the  
7 notice-and-comment period required under APA § 553 with respect to the Rules, which this Court  
8 found to be previously lacking.  
9

10 Section 553(b) requires that an agency provide notice, an opportunity to be heard, and  
11 publication of a final rule no less than 30 days before it is to go into effect. Plaintiffs have now  
12 had that full and timely notice and ample opportunity for comment, and have participated in that  
13 process. See Second PI Mot. at 15 n.17. Indeed, the Agencies received and considered around  
14 110,000 public comment submissions, and detailed their consideration of those submissions in  
15 their final rulemaking. See 83 Fed. Reg. 57,540 (religious rules); 83 Fed. Reg. at 57,596 (moral  
16 rules). The Agencies also made changes in response to those comments, see 83 Fed. Reg. at  
17 57,556-73; *id.* 57,613-26 (highlighting comments, responses, and changes). Although Plaintiffs  
18 may disagree with those changes, or with the proposal generally, it is not the place of Plaintiffs, or  
19 this Court, to substitute their judgment for that of the Agencies. See *Citizens to Preserve Overton*  
20 *Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Instead, the Court should consider whether the  
21 Agencies examined the relevant data and articulated a satisfactory explanation for their actions,  
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25 <sup>22</sup> Plaintiffs also argue that the IFRs were not validly promulgated. SJ Mem. at 58–59. As noted  
26 earlier, Plaintiffs' claims as to the IFRs are moot. *California v. Azar*, 911 F.3d 558, 569 (9th Cir.  
27 2018) ("If the final rules become effective as planned on January 14, there will be no justiciable  
controversy regarding the procedural defects of IFRs that no longer exist.").



1 including a “rational connection between the facts found and the choice made,” which they plainly  
 2 did. *Motor Vehicle Mfrs. Ass’n.*, 463 U.S. at 43 (internal quotation omitted).

3 Plaintiffs continue to claim that the Agencies are using “post-promulgation comments” to  
 4 “replace pre-promulgation comments.” SJ Mem. at 57. But the Agencies are now defending the  
 5 final version of the Rules, which were promulgated after a period of notice and comment, not the  
 6 IFRs, which were promulgated contemporaneously with the Agencies’ request for comment. The  
 7 cases Plaintiffs rely upon are solely concerned with agencies’ efforts to defend rules intended to  
 8 take effect prior to the completion of notice and comment rulemaking, like the IFRs.<sup>23</sup> They  
 9 provide no basis to invalidate the Rules, which were only finalized after the Agencies received and  
 10 addressed public comments, including from Plaintiffs.

12 In *Pennsylvania*, the district court reached a contrary conclusion by relying heavily on  
 13 *NRDC v. EPA*, 683 F.2d 752 (3d Cir. 1982), where the Third Circuit upheld a challenge to an  
 14 interim rule that indefinitely suspended the implementation of certain Clean Water Act  
 15 Amendments. *Id.* at 768. This was error. Although the Third Circuit’s remedy in *NRDC* included  
 16 enjoining a later rule to “further suspend” the amendments, which *had* been promulgated with  
 17 notice and comment, this aspect of the Court’s ruling was *not* based on procedural inadequacy of  
 18 the “further suspen[sion]” rules. *See id.* at 757. Instead, the Court enjoined both rules because the  
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21 <sup>23</sup> *Nat. Res. Def. Council v. Nat’l Highway Traffic & Safety Admin.*, 894 F.3d 95, 113–15 (2d Cir.  
 22 2018) (holding agency violated the APA by promulgating a rule without notice and comment  
 23 after rejecting the agency’s “good cause” defense); *United States v. Brewer*, 766 F.3d 884, 887–  
 24 90 (8th Cir. 2014) (rejecting attorney general’s assertion of “good cause” to bypass notice and  
 25 comment and pre-enactment publication of regulation regarding sex offender registration);  
 26 *United States v. Reynolds*, 710 F.3d 498, 509–23 (3d Cir. 2013) (same); *United States v. Dean*,  
 27 604 F.3d 1275, 1278–82 (11th Cir. 2010) (*affirming* attorney general’s invocation of good cause  
 in order to bypass the APA’s notice and comment requirement); *U.S. Steel Corp. v. EPA*, 595  
 F.2d 207, 213–16 (5th Cir. 1979) (setting aside designations promulgated without notice and  
 comment and rejecting agency arguments of good cause and harmless error), *reh’g granted*, 598  
 F.2d 915 (5th Cir. 1979).

1 question on which the public commented, *i.e.*, whether to “further suspend” the amendments, was  
2 not the question that would have been asked had the APA been followed. The question “would  
3 have been whether the amendments, which had been in effect for some time, should be suspended,  
4 and not whether they should be further postponed.” *Id.* at 768. The *Pennsylvania* court ignored  
5 this distinction between *NRDC* and the Agencies’ promulgation of the exemptions here, and this  
6 Court should not adhere to its reasoning.

7  
8 Unlike *NRDC*, the question posed to the public for comment here was the same question  
9 that would have been posed had the IFR been an NPRM. Moreover, the IFRs were enjoined shortly  
10 after they went into effect, mitigating any concerns that the Agencies had a thumb on the scale to  
11 avoid “upsetting the status quo by amending a rule only recently implemented.” *Levesque v. Block*,  
12 723 F.2d 175, 187–88 (1st Cir. 1983). Thus, even given this Court’s prior conclusion that the IFRs  
13 were procedurally defective, the proper remedy is one the Plaintiffs have already received—notice  
14 of the proposed rule and an opportunity for comment. *See Sharon Steel Corp. v. EPA*, 597 F.2d  
15 377, 381 (3d Cir. 1979); *see also U.S. Steel*, 595 F.2d at 215 (ordering EPA to “give notice of the  
16 proposed designation[s]” that were set aside on appeal “and allow comment in accordance with §  
17 553” after remand to the agency). Plaintiffs took advantage of that opportunity by submitting  
18 comments before issuance of the Final Rules, and the Agencies considered those comments in  
19 issuing the Final Rules. *See* Second PI Mot. at 15 n.17. Plaintiffs thus have suffered no remediable  
20 procedural injury. On the contrary, the Rules amply reveal that the Agencies “present[ed] evidence  
21 of a level of public participation and a degree of agency receptivity that demonstrate that a ‘real  
22 public reconsideration of the issued rule’ has taken place.” *Levesque*, 723 F.2d at 188.

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24  
25 No Ninth Circuit case cited by Plaintiffs suggests that final rules promulgated after a proper  
26 notice-and-comment period are procedurally invalid as a consequence of the issuance of  
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improperly justified IFRs. To the contrary, the Ninth Circuit has previously suggested that a final rule may be valid notwithstanding the invalidation of a prior interim rule for failure to provide notice and comment. *See Paulsen v. Daniels*, 413 F.3d 999 (9th Cir. 2005) (invalidating an interim rule for failure to comply with notice-and comment procedures and holding that the rule in effect was the final rule, where the rule previously in force erroneously interpreted a statutory provision); *Buschmann v. Schweiker*, 676 F.2d 352 (9th Cir. 1982) (invalidating interim rule and accepting parties' agreement, without discussion, that the final rule was valid). And the Ninth Circuit has also recognized that even where an agency has been found to have improperly dispensed with notice and comment procedures, the proper remedy is to offer the lost opportunity to comment rather than enjoining the rules. *See Western Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 812-13 (9th Cir. 1980) (in a case in which petitioners had not been afforded the opportunity to comment on an EPA rule, "[t]he proper remedy . . . is a reenactment of the deliberative process with correct provision for the petitioners' participation"). That participation has already been afforded to Plaintiffs, who have thus suffered no remediable procedural injury.

## **VII. Even if Plaintiffs Prevail, A Set-Aside Is the Only Appropriate Remedy**

Should the Court rule in favor of the Plaintiffs on the merits, the APA dictates the appropriate remedy: the "set[ting] aside" of the agency action deemed unlawful by the Court. 5 U.S.C. § 706(2)(A) & (D).<sup>24</sup> The matter should then be "remand[ed] to the [A]genc[ies] for additional investigation or explanation." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). Plaintiffs suggest that the Court should enter further relief in the form of a declaratory

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<sup>24</sup> The Court should not set aside portions of the Rules that permit issuers and plan sponsors to offer plans to individuals that account for sincerely-held objections the individual may have; Plaintiffs do not demonstrate any harm from that aspect of the Rules. Also, the Rules have severability provisions, to which the Court should conform any ruling. *See, e.g.*, 83 Fed. Reg. at 57,589.

1 judgment or permanent injunction against the Agencies. SJ Mem. at 60. But their motion does  
2 not articulate why the Court needs to go beyond the relief afforded under § 706. If the Rules are  
3 set aside as to the Plaintiffs, the responsibility falls to the Agencies, not Plaintiffs or this Court, to  
4 reconsider how best to address the tension between contraceptive coverage and religious freedom  
5 interests that the Supreme Court asked the Agencies to navigate in *Zubik*.

6       The scope of this “set aside”—or, indeed, any form of relief the Court may enter—also  
7 must be limited to the parties before this Court. Under Article III, a plaintiff must “demonstrate  
8 standing . . . for each form of relief that is sought.” *Town of Chester v. Laroe Estates, Inc.*, 137 S.  
9 Ct. 1645, 1650 (2017) (quotation omitted); *see also Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018)  
10 (a “plaintiff’s remedy must be limited to the inadequacy that produced his injury in fact” because  
11 “the Court’s constitutionally prescribed role is to vindicate the individual rights of the people  
12 appearing before it.”). Although the Ninth Circuit’s decision in *Earth Island Inst. v. Ruthenbeck*,  
13 490 F.3d 687, 699 (9th Cir. 2007), *rev’d in part on other grounds sub nom. Summers v. Earth*  
14 *Island Inst.*, 555 U.S. 488 (2009), asserted that a “nationwide injunction . . . is compelled by [§  
15 706] of the Administrative Procedure Act,” this Court has acknowledged that “*Earth Island Inst.*  
16 recognized that a nationwide injunction is discretionary relief” that must be analyzed in light of  
17 recent “Ninth Circuit guidance” about the permissible scope of relief in an APA action, even when  
18 considering final relief under section 706. *City & Cty. of S.F. v. Sessions*, 349 F. Supp. 3d 924,  
19 971 n.7 (N.D. Cal. 2018), *appeal filed*, No. 18-17308 (9th Cir. 2018); *see also California*, 911  
20 F.3d at 582–84. As this Court previously explained, Plaintiffs have failed to meet “the high  
21 threshold set by the Ninth Circuit for a nationwide injunction,” particularly in light of concerns  
22 that “parallel litigation” ongoing in courts in the First and Third Circuits may lead to “direct legal  
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conflicts” between this Court and others.<sup>25</sup> Order Granting Pls.’ PI Mot. at 44. “[A]n injunction that applies only to the plaintiff states would provide complete relief” to them, *California*, 911 F.3d at 584, and Plaintiffs adduce no further evidence in their summary judgment motion to support a contrary conclusion. As such, the Rules should be “set aside” with respect to the named Plaintiffs only.

### **CONCLUSION**

For the reasons stated above, the Court should dismiss this suit or, in the alternative, enter judgment in favor of Federal Defendants.

Dated: May 31, 2019

Respectfully submitted,

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<sup>25</sup> It is of no moment that the First Circuit recently reversed the holding of a district court in Massachusetts that the state plaintiff in that case lacked standing to bring similar claims. *Massachusetts v. U.S. Dep’t of Health & Human Servs.*, 923 F.3d 209 (1st Cir. 2019). It remains the case that interlocutory, merits, and appellate proceedings in other courts may be disrupted by the entry of nationwide relief here.